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BRH BULLETIN

bureau of radiological health

Monday, January 18, 1982 • Volume XVI, No. 1

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97th Congress Enacts Technologist Credentialing Legislation

On August 13, 1981, President Reagan signed into law the "Omnibus Budget Reconciliation Act of 1981" (P.L. 97-35), a part of which contains the "Consumer-Patient Radiation Health and Safety Act" introduced by Senator Jennings Randolph in March 1981. The Act requires the federal government to establish minimum standards for state health agencies to use as a guide in establishing certification and accreditation programs for nonpractitioner medical radiologic technologists, dental auxiliaries, radiation therapy technologists, and nuclear medicine technologists. A second major component of the Act calls for the development of medical radiation guidelines for voluntary application in the private sector and mandatory use in federal health care facilities. The guidelines, intended to reduce unnecessary patient exposure, could address issues such as unnecessary mass screening and repeat examinations, referral criteria, quality assurance techniques, and exposure guidelines.

On January 5, 1982, Dr. Edward Brandt, Assistant Secretary for Health in the Department of Health and Human Services (HHS) assigned primary responsibility for the development of the credentialing standards to the Health Resources Administration. The Food and Drug Administration, according to Dr. Brandt's directive, is charged with the task of developing the radiation guidelines and ensuring their adoption by federal agencies.

Under the credentialing provisions of the Act, the Secretary of HHS must work with professional certifying and accrediting organizations, states, and others to develop both the voluntary credentialing standards and a model statute that provides the framework for state-based credentialing programs. This work must be completed by August 1982, one year after the enactment of P.L. 97-35. The Secretary is also required to monitor state acceptance and use of these standards, and to report annually to the Congress on progress in this area. The Act provides that after a 3-year period, the Secretary may propose legislative changes to ensure universal credentialing of the technologist groups covered in the Act.

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Publications Moratorium Continues

The Department of Health and Human Services continues under a Presidentially mandated publications moratorium that was issued in April 1981. The publications issued since that time by the Bureau of Radiological Health were previously approved by the Department.

As long as the moratorium continues, the Department will not approve new documents for publication, and the Bureau cannot send these unapproved documents to the Government Printing Office (GPO) for printing. Instead, the Bureau will be sending any documents initiated and completed since the moratorium was issued to the National Technical Information Service (NTIS), where they will be announced and made available for sale as "blowback" paper copies from microfilm or as microfiche copies. GPO normally does not sell publications that have not been initially printed by the originating Agency, so these "new" reports will be available only from NTIS. Availability of all such publications will be announced in the BRH Bulletin.

When the moratorium is lifted, apart from an expected more restrictive review process, the Bureau will offer a reduced publications program consistent with current budget limitations. One example of the Bureau's attempt to reduce unnecessary costs associated with the mailing of publications is the "BRH Mailing List Retention Notice" dated December 6, 1981. This notice was mailed to all addressees presently on the Bureau's publications mailing system. If an addressee has not returned the green-colored retention form, that person will be removed from the Bureau's mailing lists during February 1982.

The Bureau also is cutting publishing costs by reducing the number of copies printed for free distribution and publicizing the availability of documents for purchase from GPO and/or NTIS.

In another effort to reduce publishing costs, the BRH Bulletin has been changed from a biweekly to a monthly periodical. All such periodicals require approval by the Office of Management and Budget. If approval for publishing the BRH Bulletin is not obtained prior to March 1982, the BRH Bulletin, in its 16th year of publication, may not be continued.

Bureau Finds New Data on Effects of Microwave Radiation on Mouse Cells

The Bureau of Radiological Health's Division of Biological Effects recently completed the first scientific study that quantitatively measures the dose-dependent effects of microwave radiation on cell division and chromosome damage of spermatogenic cells in mice.

The study was performed by direct examination of three phases in the maturation of the spermatogenic cells. It was developed for 2.45-gigahertz microwave radiation exposure, but experiments were also performed at 0.915 gigahertz and 9.4 gigahertz. Effects were seen at all three frequencies.

Each maturation phase responded to microwave exposure, but with qualitative and quantitative differences among both the phases and the microwave frequencies

studied. Chromosomal abnormalities, cell degeneration, and cell death were detected. These changes may lead to partial or complete temporary sterility in mice. Breeding experiments are underway to confirm this possibility.

Data from these experiments will be used to form the basis for further studies on the genetic transmissibility of chromosomal effects to offspring, and eventually for quantitative assessment of the genetic risk associated with microwave exposure.

Radiologic Imaging Studies in Progress

In the area of radiologic imaging, a major advance has been made toward the formation of a consensus measurement methodology for specifying the performance of radiographic intensifying screen systems. Recent collaborative efforts between the Bureau of Radiological Health's Division of Electronic Products (DEP) and the Los Alamos National Laboratories have led to development of a technique for intercalibrating microdensitometers that measure signal-to-noise ratios from x-ray film. The ultimate goal is consensus measurement and specification of radiographic speed, contrast, resolution, and signal-to-noise performance. This is being pursued through measurement intercomparisons among 10 laboratories worldwide--a program that grew out of a cooperative effort between the Bureau and the University of Chicago about a year ago.

As a result of other imaging research by scientists from DEP and the University of British Columbia, the first in a series of three papers--"Efficiency of Human Visual Discrimination"--has been published in Science (volume 214, pages 93-94, 1981). The paper indicates that under certain ideal conditions the human observer of noisy images (radiographic, radioisotope, or computed tomographic) can approach the performance allowed by the fundamental limitations imposed by statistical fluctuations in x-ray counts. The results will be useful in studying image processing and methods of assessing medical imaging system performance.

During December 1981, Dr. Charles E. Metz of the University of Chicago visited the Bureau to work with DEP scientists on the problem of defining the limits of accuracy in assessing the performance of a medical imaging system with a limited number of phantom images. Several independent solutions were found that agree with each other.

For further information on the Bureau's radiologic imaging studies, please contact Dr. Robert F. Wagner, Bureau of Radiological Health (HFX-250), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5020.

X-Ray Compliance Videotapes Available for Purchase

The announcement in the November 9, 1981, BRH Bulletin that the videotapes, "Routine Compliance Testing for Diagnostic X-Ray Machines," are available for free loan from the Bureau of Radiological Health was an error. Instead, the

programs may be purchased individually or as a series from the National Audiovisual Center (NAC), National Archives and Records Service, General Services Administration, Order Section, Washington, D.C. 20409.

The tapes depict the new procedures described in the manual, "Routine Compliance Testing for Diagnostic X-Ray Systems." It is recommended that interested persons read and become familiar with the appropriate sections of the manual before viewing any of the videotape programs. The manual is available for sale from the National Technical Information Service, Springfield, Virginia 22161. The NTIS accession number is PB 81-201501, and the price is $15.50 per paper copy and $4.00 per microfiche copy.

The videotapes are available in Beta 2, VHS, and 3/4-inch formats. There is a separate order number for each format of each title. These are listed below along with the price.

- Series of seven videotapes, "Routine Compliance Testing for Diagnostic X-Ray Machines," 1981, Color, $375.
  3/4-inch Order No. A06724
  Beta 2 Order No. A06725
  VHS Order No. A06726

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Peak Kilovoltage Determination," 10 minutes, 1981, Color, $45.
  3/4-inch Order No. A06719
  Beta 2 Order No. A06720
  VHS Order No. A06721

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Abovetable X-Ray Source, Radiographic Systems," 30 minutes, 1981, Color, $65.
  3/4-inch Order No. A04226
  Beta 2 Order No. A06722
  VHS Order No. A06723

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Abovetable X-Ray Source Fluoroscopic and Spot Film Systems," 14 minutes, 1981, Color, $55.
  3/4-inch Order No. A06704
  Beta 2 Order No. A06705
  VHS Order No. A06706

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Mobile Radiographic Systems," 16 minutes, 1981, Color, $55.
  3/4-inch Order No. A06716
  Beta 2 Order No. A06717
  VHS Order No. A06718

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Mammographic Systems," 13 minutes, 1981, Color, $55.
  3/4-inch Order No. A06707
  Beta 2 Order No. A06708
  VHS Order No. A06709

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Dental Radiographic Systems," 12 minutes, 1981, Color, $55.
  3/4-inch Order No. A06710
  Beta 2 Order No. A06711
  VHS Order No. A06712

- "Routine Compliance Testing for Diagnostic X-Ray Machines: Undertable Source Fluoroscopic and Spot Film Systems," 28 minutes, 1981, Color, $65.
  3/4-inch Order No. A06713
  Beta 2 Order No. A06714
  VHS Order No. A06715

When ordering, please state the title, the order number for the format you want for each title, and the price. Also, please add a $5 handling charge for each order.

Cassettes may be purchased by purchase order, direct payment, or with a VISA or MasterCard. For invoicing, an official purchase order or letter on organizational letterhead is required. For direct payment, please make checks or money orders payable to: National Archives Trust Fund (NAC). Only mail orders will be accepted. Orders should be sent to the National Audiovisual Center at the address given in the first paragraph.

Prices of the programs are subject to change without notice. Please allow 4 to 6 weeks for delivery. Preview and rental are not available for the videotapes. For questions regarding any of the titles, please call NAC at (301) 763-1896.

Corrective Action Plans

During December 1981, the Bureau of Radiological Health approved two corrective action plans for products found in noncompliance with performance standards issued under the Radiation Control for Health and Safety Act. The products involved are:

- 249 Picker "Astro" fluoroscopic x-ray controls, model numbers 755-270A and 755-270B, serial numbers 1003-1308, manufactured by Picker International of Highland Heights, Ohio. While 306 of these units were originally produced, only 249 were introduced into U.S. commerce and remain to be corrected. The "Astro" controls were found in noncompliance with the federal performance standard for diagnostic x-ray systems because they failed to meet the entrance exposure rate requirements of the standard. Picker's corrective action plan consists of notifying all users of the noncompliance, visiting the site of each unit to add a circuit to control the entrance exposure rate for line voltage variations, and recalibrating each unit according to revised calibration instructions. Picker will not charge users for these repairs.

- 60 Shimadzu mobile x-ray units, model MC125L-30, manufactured by the Shimadzu Corporation of Kyoto, Japan, and imported into the U.S. by Hansen Medical Enterprises, Inc., of San Clemente, California. Based upon review of the initial report submitted to the Bureau and laboratory

testing at FDA's Winchester Engineering and Analytical Center, the units were found to be in noncompliance with 11 requirements of the federal performance standard for diagnostic x-ray systems. The violations included linearity, reproducibility, beam quality, and errors in or incomplete user information. The corrective action plan calls for Hansen dealers to visit the site of each unit to make physical corrections and provide purchasers with new user information. Hansen will notify all users of the noncompliance and will send additional literature, labels, parts, and instructions to the dealer who sold and assembled each unit. Dealers will visit user sites and correct the units by modifying a circuit and rendering the "S" setting on the mAs dial unselectable. All corrections will be made at no cost to users.

February 1982 Calendar of Events

The following is a list of February 1982 meetings of relevance to Bureau activities and the talks and exhibits to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Seminar in a Series on the Biological Effects of Electromagnetic Fields, hosted by JAYCOR and supported by the Office of Naval Research. To be held at the Uniformed Services University of Health Sciences, Bethesda, Maryland, February 2.

"Meiotic Chromosome Aberrations and Their Biological Significance Following Microwave Exposure," Ewa Manikowska-Czerska, Guest Worker, Division of Biological Effects.

Annual Meeting of the Environmental Mutagen Society, Boston, Massachusetts, February 26 - March 2.

"Normal Behavior by Human Cells Possessing an Intermediate Defect in Post-Replication Repair," Victoria K. Hitchins, Elizabeth D. Jacobson, Denise C. Knott, and Carl D. Lytle, Division of Biological Effects.

"The Relationship Between Ultraviolet Light-Induced Sister Chromatid Exchange and Mutations in 'Mutiacus Muntjak' (Indian Muntjac) Skin Fibroblasts," Maria H. Lugo, Elizabeth D. Jacobson, and Kenneth Krell, Division of Biological Effects.

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BRH BULLETIN
bureau of radiological health

Tuesday, February 16, 1982 • Volume XVI, No. 2

In this issue:
- Announcement of Annual Radiation Control Conference
- Slide/Tape Package for RT's on Mammography
- Reminder Regarding Mailing List Retention Notice
- New Bureau Publications

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14th Annual Radiation Control Conference To Be Held in Portland, Maine

The 14th Annual National Conference on Radiation Control will be held Monday, May 24, through Thursday, May 27, 1982, at the Holiday Inn Downtown in Portland, Maine. As in previous years, the meeting will be cosponsored by the Conference of Radiation Control Program Directors, Inc., FDA's Bureau of Radiological Health, the Environmental Protection Agency's Office of Radiation Programs, and the Nuclear Regulatory Commission. The American College of Radiology (ACR) will continue its formal participation in the annual meeting by cosponsoring a plenary session on the afternoon of May 25, and will also participate in other parts of the program. More than 300 representatives of federal, state, and local radiation control agencies, professional organizations, industry, and others concerned with radiation protection, use, and control are expected to attend.

The program has been planned to cover most aspects of radiation control but will concentrate on priorities and how they are established. The opening session on May 24 will feature state and federal officials discussing their activities and the problems that face their agencies in protecting the public from radiation exposure in the context of today's political and economic environments.

The program on the morning of May 25 is entitled "Radiation Facts and Fantasies." The session will feature a panel discussion by speakers who will present their views of the public's perception of radiation and the effectiveness of various methods of communicating information on this controversial subject. The formal presentations will be followed by discussions and questions from the floor.

The May 25 afternoon program, sponsored in cooperation with the ACR, will be devoted to three areas of concern to the healing arts profession and radiation control personnel: (1) fees to support a state program, (2) credentialing of individuals who perform radiologic procedures, and (3) problems of protection associated with advances in radiation technology. Following panel discussions of these three topics, the traditional unstructured session with representatives of the ACR and other meeting participants will be held. This unstructured session, which has proven to be very informative and productive since its inception five years ago, will provide an opportunity for all interested attendees to discuss problems in the application and control of radiation with respect to diagnostic radiology.

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The May 26 morning session will focus on the various activities presently being conducted by a comprehensive state radiation control program. Of these activities, those worth saving or doing will be identified from the viewpoints of the medical profession, regulated industry, and the general public. Following the presentations and discussion, a number of state program directors will explain how and why they establish priorities. In view of the current political and economic environment, this is a very timely subject, and the discussions are expected to cover recommendations for priority setting.

The May 26 afternoon session will cover a variety of topics, including the federal performance standard for diagnostic x-ray systems, the use of x-ray intensifying screens, the NEXT (Nationwide Evaluation of X-Ray Trends) program, radio-frequency (RF) dielectric heaters and sealers, state regulations for nonionizing radiation, and the environmental problems associated with radon buildup.

Thursday, May 27, will be devoted to discussions of emergency planning and preparedness and will focus on the costs associated with planning as well as other costs. The use and distribution of potassium iodide will be addressed. Consideration also will be given to low-level waste criteria, compacts, and regulations and a number of other current issues and concerns associated with radioactive waste disposal.

The meeting is open to all persons interested in the use and control of radiation. Additional information is available from Wallace Hinckley, Manager, Radiological Health Program, Maine Department of Human Services, 157 Capitol Street, Augusta, Maine 04333, telephone (207) 289-3826.

RT Training Package on Mammography Being Made Available for Purchase

The Bureau-developed series of slide-tape training packages for radiologic technologists has been expanded to include a new part titled "Film/Screen Mammography: Physics and Quality Assurance." The new package (part 7 of the series) is being made available for sale by the National Audiovisual Center (NAC).

The slide-tape series, "Radiation Protection During Medical X-Ray Examinations," is a training program designed to teach radiologic technologists how to protect patients and themselves from unnecessary x-ray exposure. With the addition of the part on mammography, the series now consists of seven parts, each of which covers a different topic in radiation protection.

Each part contains a set of 2- by 2-inch slides, a cassette tape recording of the text, a printed text that coincides with the recording, instructions for using the complete package, and suggestions for modified use. Parts 4, 5, and 6 also contain supplemental material for the presenter's use. Some of the features are: (1) the tapes incorporate both audible and inaudible pulses to allow either manual slide change or operation with automatic slide systems, (2) the slides and tapes are adaptable to commonly used audiovisual equipment, (3) the text includes reproductions of the slides to assist in correlation, and (4) additional space is provided in the text so that the presenter may include his or her own material. The parts are designed so that each may be presented by itself or in conjunction with other parts. The modular format permits new parts to be added as needed so users will have a growing, uniform, and up-to-date library of training materials on x-ray protection.

The packages have been used succesfully for student technologist training (indivdual and group), practicing technologist refresher courses, in-service education programs, professional meetings, exhibits, seminars, and self-learning. In addition, they have been approved for the granting of "Evidence of Continuing Education" points by the American Society of Radiologic Technologists.

The first three parts were issued in 1973. Part 1 covers the principles of x-ray protection, part 2 presents a simple method for checking the alignment of the light beam in a collimator, and part 3 explains a method for calculating the beam size from a cone using only simple arithmetic. Parts 4 and 5, which were released for sale in 1976, deal respectively with the biological effects of x rays and the establishment of an effective gonad shielding program, and part 6, released in 1978, presents an overview of the procedures for establishing a basic quality control program for an automatic film processor.

The new package on mammography, part 7, describes the radiographic characteristics of the breast and explains how they relate to the production of good mammograms. The use of low-energy x rays, their importance in mammography, and their effect on patient exposure and image quality also are discussed. A comparison is made of the advantages and disadvantages of special-purpose and general-purpose x-ray units. In addition, this part explains why specially designed mammographic film/screen combinations are necessary for adequate imaging of the breast.

Those who wish to purchase these materials may order either the complete series or the individual parts from the National Audiovisual Center, National Archives and Records Service (GSA), Washington, D.C. 20409.

The Bureau has prepared a pamphlet that describes the packages and contains a form for ordering them from NAC. Copies of the pamphlet may be obtained by writing to the Bureau of Radiological Health (HFX-73), 5600 Fishers Lane, Rockville, Maryland 20857, or by calling (301) 443-4647.

A Bureau-developed slide/tape training package for nuclear medicine personnel, "Radiation Protection for Nuclear Medicine Procedures: Part I, Principles of Protection for Diagnostic Examinations," is also available for purchase from NAC (BRH Bulletin, May 4, 1981). A pamphlet about this package and a form for ordering it may be obtained from the Bureau of Radiological Health at the above address.

Reminder To Respond to BRH Mailing List Retention Notice

Recipients of the BRH Bulletin and other Bureau of Radiological Health publications who wish to continue receiving these materials are reminded to return the green-colored mailing list retention notice that was mailed in late December 1981. Only those persons who respond to the notice will receive publications issued by the Bureau in the future. The names and addresses of those who fail to return the notice will be placed in an inactive file and deleted from the Bureau's current mailing lists.

Anyone who has not received the green retention form or who has lost or misplaced the form and wishes to remain on the mailing list should write to the Bureau of

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Radiological Health (HFX-25), 5600 Fishers Lane, Rockville, Maryland 20857, or call (301) 443-3434.

New Bureau Publications

The following publications are available for purchase from either the Government Printing Office or the National Technical Information Service, as indicated in the parentheses following the citation.

"11th Annual National Conference on Radiation Control - Radiation: Mininizing Exposure: Optimizing Use, May 6-10, 1979, Oklahoma City, Oklahoma" (FDA 81-8054), proceedings compiled by the Bureau of Radiological Health. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-102575, $31.50 per paper copy, $4.00 for microfiche.)

"A Primer on Theory and Operation of Linear Accelerators in Radiation Therapy" (FDA 82-8181), C. J. Karzmark, Stanford University, and Robert J. Morton, Division of Training and Medical Applications. (Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; Stock No. 016-015-00204-7, $4.25 per copy.)

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Monday, March 15, 1982 • Volume XVI, No. 3

In this issue:

- New Agreement on Medical Device Responsibilities
- Guidelines for Clinical Trials of NMR Systems
- Legal Judgment Against Xonics Medical Systems
- Status of Physician Referral Criteria Panels
- Linear Accelerator Report and Videotape
- April 1982 Calendar

BRH To Assume Greater Responsibility for Radiation-Emitting Medical Devices

Effective April 1, 1982, the Bureau of Radiological Health will assume greater responsibility for regulating radiation-emitting medical devices. The added responsibilities are defined in a new agreement regarding the working relationships that will exist among the Bureau of Medical Devices (BMD), Bureau of Radiological Health (BRH), and Bureau of Biologics (BoB) for certain specifically identified medical devices. The agreement was approved by Deputy Food and Drug Commissioner Mark Novitch on February 5, 1982.

Since the enactment in 1976 of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FD&C Act), BMD has taken the lead responsibility within the Agency for developing and implementing programs under these authorities. Before and since that time, BRH has been responsible for controlling electronic product radiation under the Radiation Control for Health and Safety Act, and BoB has been responsible for the licensure of biological products under the Public Health Service Act. Since some medical devices are also radiation-emitting products, licensed biologicals, or used in the production of biological products, the potential existed for overlapping administration or duplication of efforts by these two Bureaus and BMD. There also was potential for public confusion as to which Bureau was responsible for regulating particular products. In 1979 a document was prepared that detailed the working relationships between BMD and BRH and identified the responsibility of each for medical device activities. The new agreement revises the 1979 version to include BoB in the working relationship and to extend further the distribution of responsibility under the FD&C Act.

The major modification to the 1979 BMD/BRH agreement is to provide for each of the three Bureaus to regulate independently the devices for which it has lead responsibility. The agreement sets forth the criteria for identifying the devices for which BRH and BoB are responsible. It lists 23 types of devices for BoB, such as blood storage refrigerators and blood bank supplies, and 188 types for BRH, such as x-ray machines and ultrasonic fetal monitors. (The BRH list is substantially unchanged from the 1979 agreement.)

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BMD will maintain lead responsibility for regulating all other medical devices, for developing major medical device policies and procedural regulations, and for certain other activities such as small business assistance and the device problem reporting program. BMD also will continue to handle all manufacturer registrations and product listings, but each Bureau will process all other submissions from industry for the devices for which it has lead responsibility. These submissions include premarket notifications, premarket approval applications, investigational device exemption applications, and reclassification petitions.

Each Bureau also will handle all surveillance and compliance actions for its assigned devices. BRH will use the authorities of the FD&C Act and the Radiation Control Act, and BoB will use the authorities of the FD&C Act and the Public Health Service Act.

Each Bureau will maintain its own advisory committees for consultation on issues related to medical devices. The Radiology Section of the Obstetrics-Gynecology and Radiologic Devices Panel will be transferred from BMD to BRH and converted into an advisory committee for all BRH devices, regardless of which panel originally classified the devices. BoB will use one of its existing committees for biologic-related devices.

Copies of the agreement, "Working Relationships Agreement Among the Bureau of Medical Devices, Bureau of Radiological Health, and Bureau of Biologics," are available from the Documents Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857. For further information, please contact Robert A. Phillips, Bureau of Radiological Health (HFX-460), at the above address, telephone (301) 443-3426.

Guidelines Developed for Clinical Studies of NMR Systems

The Bureau of Radiological Health has prepared a document titled "Guidelines for Evaluating Electromagnetic Exposure Risk for Trials of Clinical Nuclear Magnetic Resonance (NMR) Systems." The document provides guidance to Institutional Review Boards (IRBs), researchers, and sponsors of clinical investigations for use in determining whether a clinical study involving an NMR device represents a "significant risk" under the Investigational Device Exemption (IDE) regulation of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

NMR devices encompass a technology new to medicine that shows significant promise for diagnostic use. The technique relies on the ability of certain atoms such as hydrogen and phosphorous to emit characteristic signals when excited by electromagnetic pulses in a strong magnetic field. These signals emitted from atoms within the body can be used to produce an image of the body or other diagnostic information. Two characteristics make the technology potentially attractive: (1) the useful information resulting from an NMR study may, in some instances, exceed that from current radiological procedures, and (2) the process does not involve the use of ionizing radiation.

NMR devices are not commercially available at the present time. Under the Medical Device Amendments, a new medical device such as an NMR system must be shown to be safe and effective before being marketed. A Premarket Approval

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Application (PMA) is the primary method of establishing safety and effectiveness. In order to develop the scientifically valid information necessary for a PMA, new devices undergo clinical investigation under an Investigational Device Exemption (IDE), which allows use of an unproven device for investigational purposes only. NMR is now starting this phase of development.

Basic to the IDE process is the determination of whether use of a device involves "significant risk" to the patient--that is, whether it represents a "potential for serious risk to the health, safety, or welfare of a subject." Under the IDE regulation, the sponsor and ultimately an IRB have immediate responsibility for determining whether a certain clinical use of an investigational device represents a significant risk. A finding of significant risk does not mean that a device is too hazardous for clinical studies, but it does mean that a formal application must be made to FDA for an IDE. Through the FDA review process, the safety aspects of the particular study will be independently evaluated. Generally, if the IRB finds that a proposed study does not present a significant risk to patients, submission of an IDE application to FDA is not necessary.

Because of the limited information available on the biological effects associated with the use of NMR in clinical medicine, the Bureau developed the guidelines to assist sponsors of clinical trials and members of IRBs in determining when a study involving an NMR system might be regarded as a significant risk to the subject with respect to static, changing, or radiofrequency magnetic fields. The guidelines are intended to prevent submission of IDE applications to the Agency when they are not necessary to assure the safety of clinical subjects.

The guidelines address three areas of concern: (1) whole or partial body exposure to static magnetic fields, (2) whole or partial body exposure to time-varying magnetic fields, and (3) absorption of energy from radiofrequency electromagnetic fields. On the basis of current information, the Bureau believes that a study which does not exceed the limits specified in the guidelines probably does not present an unacceptable risk in these three areas. In the absence of definitive bioeffects information, however, the levels chosen for the guidelines must be considered interim and somewhat arbitrary. Furthermore, the application of the guidelines is limited, and they should not be construed as general safety recommendations for workers or the general public. As bioeffects research continues and more clinical data become available, the guidelines will be refined and amended by the Bureau.

Copies of the guidelines have been sent to manufacturers, researchers, and sponsors of clinical studies for review. These and other interested persons are invited and encouraged to submit comments on the guidelines. Submissions should cite Docket Number 82D-0053 and be addressed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857. For additional information or to obtain copies of the guidelines, please contact Robert A. Phillips, Bureau of Radiological Health (HFX-460), at the above address, or call (301) 443-3426.

Physician Referral Criteria Panels Continue Development Efforts

Over the past three years, the Bureau of Radiological Health has participated in a successful cooperative program with the medical community to develop referral

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criteria for specific x-ray examinations and to promote their adoption by medical professionals. Four physician panels have been convened thus far as part of this voluntary cooperative effort.

The convening of such expert panels to assess the literature on the efficacy of specific radiological examinations and to suggest, if possible, guidelines for their appropriate use was a major strategy developed at the National Conference on Referral Criteria for X-Ray Examinations, held in Washington, D.C., October 25-27, 1978. During the Conference, it was also suggested that review of these guidelines be coordinated by members of the radiology community. In response, the American College of Radiology (ACR) has established a special advisory committee under Dr. Robert Mosely that has been coordinating medical society review of referral criteria sets.

The four physician panels have reviewed x-ray pelvimetry, voiding cystourethrography in children, chest x-ray screening examinations, and skull x-ray examinations following trauma. The status of each of these panels is described below.

The Pelvimetry Panel has met twice and developed a statement emphasizing the lack of efficacy of the pelvimetry x-ray examination. This statement was adopted as policy by the ACR, and a similar statement was adopted by the American College of Obstetricians and Gynecologists and promoted by them in their Quality Assurance Manual. Both college statements as well as background information on the subject were published in a Bureau report, "The Selection of Patients for X-Ray Examinations: The Pelvimetry Examination." The report may be purchased from the Government Printing Office, Washington, D.C. 20402 (stock number 017-015-00174-1, $2.00 per copy). In addition, the pelvimetry statement has served as the basis of a nationwide educational program sponsored by the Health Care Financing Administration. Although final results of that program are not expected until later this year, preliminary findings indicate that the program has had a major impact in reducing inefficacious pelvimetry examinations and in demonstrating the effectiveness of a purely educational approach for implementing referral criteria.

The Voiding Cystourethrography Panel has met once to assess the use of this examination in children. A draft panel report was developed that identified some instances where this examination was appropriately ordered and some where it was not. The panel identified a number of circumstances where the members believed the evidence was inconclusive and recommended additional controlled research on the subject. To date, it has not been possible to fund such research because of budget constraints.

The Chest X-Ray Panel has met several times over the past two years and has developed draft referral criteria statements on five screening uses of this examination. These include routine mandated chest x-ray screening, prenatal screening, hospital admission screening, tuberculosis detection and control, and occupational screening. These draft statements and background information were made available for public review in a draft panel report. The availability of this report was announced in the BRH Bulletin of March 9, 1981, and in the Federal Register (46 FR 30568). The draft statements are currently being reviewed by several medical specialty societies.

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The Skull X-Ray Panel is presently reviewing existing data and literature on the use of the conventional skull x-ray examination in patients with head trauma. It is also reviewing existing referral criteria for the use of this examination, with the objective of developing a consensus set of guidelines for safe and effective use.

Although progress on the referral criteria program has been slowed because of reduced operating budgets, private sector initiatives to develop and test referral criteria have grown substantially since 1978. Not only are increasing numbers of articles appearing in the literature, but several professional societies have expressed an increased interest in clinical decisionmaking. Furthermore, the concept of referral criteria and the panel approach will be expanded internationally this fall when the World Health Organization convenes a special meeting on the subject. For the Bureau's part, plans for future panels and studies have been developed and will go forward as budget authorizations permit.

For more information regarding the panels and their recommendations, please contact Harvey Rudolph, Bureau of Radiological Health (HFX-76), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-4600.

Xonics Medical Systems Fined $15,000 for Violations of X-Ray Standard

Xonics Medical Systems, Seattle, Washington, and two of its employees--the branch manager and the service manager--have been fined $15,000 for violations of the federal performance standard for diagnostic x-ray systems. The firm is engaged in the business of installing and assembling diagnostic x-ray equipment.

FDA's Seattle District Office filed the complaint against the firm in the U.S. District Court for the western district of Washington. The complaint cited the firm for the following infractions of the x-ray standard:

- Issuing false and misleading certifications of compliance to purchasers. FDA testing of several installations after assembly and certification by the firm revealed that the installations failed to comply with the x-ray field collimation requirements of the standard.

- Failing to bring a diagnostic x-ray system into compliance after being notified by FDA that the installation did not comply with the standard.

- Failing to issue assembler certifications to purchasers of diagnostic x-ray assemblies.

- Failing to report installations of diagnostic x-ray systems to the Bureau of Radiological Health.

- Failing to notify FDA of defects in x-ray systems installed by the firm. The firm's service records showed that multiple attempts had been made by the firm to correct a timer defect involving "multiple exposures."

The complaint was filed under the enforcement provisions of the Radiation Control for Health and Safety Act. These provisions authorize U.S. District Courts to punish violators of regulations issued under the Act through the imposition of

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civil penalties of up to $1,000 for each infraction. The firm signed a consent decree to pay the $15,000 fine on February 16, 1982.

This civil penalty action is especially significant in that it is the first completed judgment under FDA's 3-year-old policy of recommending that fines be levied against x-ray assemblers who continue to install noncompliant x-ray systems after having been warned by the Agency not to do so. Other actions are now pending.

Linear Accelerator Report and Videotape Available

The Bureau of Radiological Health recently published a report on linear accelerators (linacs) in radiation therapy and has also produced a videotape on this subject. Both were developed in cooperation with the National Cancer Institute's Division of Resources, Centers, and Community Activities. They are intended to serve as an introduction to linacs for students of radiation therapy technology, radiological physics, radiation oncology, and radiation control.

The report, "A Primer on Theory and Operation of Linear Accelerators in Radiation Therapy," describes the components of the linac, their functions, and their interrelationships. Many photographs and drawings are included.

The videotape, "Linear Accelerators in Radiation Therapy: Theory and Operation," contains three parts on a single cassette. The three parts discuss linac operation in increasing complexity; each part may be used alone. Part 1--Basic Components (12 minutes)--is a brief description of the internal and external parts of the linac, with a demonstration of an actual treatment procedure. Part 2--Function of Main Components (12 minutes)--demonstrates how the major modules function as an electronically integrated unit and discusses the auxiliary systems. Part 3--Technical Operation (18 minutes)--discusses functions of the major components from a more complex and technical perspective. Operation of microwave cavities, microwave power sources, and standing and traveling wave accelerator structures are explained.

The videotape is available for sale in 1/2-inch and 3/4-inch formats from the National Audiovisual Center (NAC). When the tape is purchased from NAC, a copy of the publication will be included at no extra charge. The videotape may also be borrowed from the Bureau's Training Resources Center on a 30-day free-loan basis (in the 3/4-inch U-matic format only). For further information on ordering the videotape, please write to the Bureau of Radiological Health (HFX-73), 5600 Fishers Lane, Rockville, Maryland 20857. The publication may be ordered separately from the U.S. Government Printing Office, Washington, D.C. 20407. Cost of the publication is $4.25 per copy, and the GPO stock number is 017-015-00204-7.

Over the past several years, an interagency agreement between the Bureau and the National Cancer Institute has resulted in the development of materials on radiation quality assurance as well as the linac materials described above. Educational programs produced through this cooperative effort include "Film/Screen Mammography: Physics and Quality Assurance" (part seven of a series of slide/tape packages titled "Radiation Protection During Medical X-Ray Examinations"), videotapes of a brachytherapy symposium, and a videotape series on "Topics in Radiation Therapy."

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April 1982 Calendar of Events

The following is a list of April 1982 meetings of relevance to Bureau activities and the talks and exhibits to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Annual Meeting of Mideastern Chapter, Society of Nuclear Medicine, Fredericksburg, Virginia, April 1-3.

"Recent Development in Gamma-Camera Performance Testing: Resolution Measurements," P. Paras, Office of the Bureau Director; G.J. Hine, Boulder, Colorado; and R. Adams, Loma Linda University.

FDA Science Research Colloquium, Bethesda, Maryland, April 1 - 2.

"Comparison of Ultraviolet Radiation-Induced Sister Chromatid Exchanges (SCEs) and Mutations in Indian Muntjac Cells," Maria H. Lugo, Division of Biological Effects.

"Enhanced Viral Reactivation: A Potential Mammalian Test System," C. David Lytle, Division of Biological Effects.

"L5178Y Mouse Lymphoma Cells with Different Efficiencies of DNA Repair: A Unique System with Potential Application in Toxicology," Elizabeth D. Jacobson and Janusz Beer, Division of Biological Effects.

"A Possible Tumor Virus Induction Test for Light and Photosensitizing Chemicals," Larry E. Bockstahler, Division of Biological Effects.

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BRH BULLETIN

bureau of radiological health

Monday, April 19, 1982 • Volume XVI, No. 4

In this issue:
Division of Biological Effects Reorganization
Announcement of Short-Lived Radionuclide Symposium
New TEPRSSC Members
Corrective Action Plan
New Bureau Publications
May 1982 Calendar

Division of Biological Effects Reorganized

The Bureau of Radiological Health's Division of Biological Effects has been reorganized into a new structure that better reflects the process by which the Bureau carries out its mission. Along with the reorganization, the Division is shifting its primary emphasis to risk assessment.

Four new branches oriented along radiation lines will carry out the Division's responsibilities. The Electromagnetic Radiation Branch will be responsible for radiofrequency, very high frequency, ultra-high frequency, microwave, and magnetic field radiation; the Ionizing Radiation and Statistics Branch will be responsible for all aspects of ionizing radiation and will provide statistical support to the Division and other Bureau components; the Light Radiation Branch will be responsible for ultraviolet, visible, and infrared radiation; and the Acoustic Radiation Branch will be responsible for all frequencies in the acoustic energy spectrum, including infrasonic, sonic, and ultrasonic radiation.

The four new branches will replace the former Experimental Studies Branch, Epidemiologic Studies Branch, and Standards Support Staff. According to the new functional statements, each of the four branches will (a) collect, maintain, review, evaluate, and provide up-to-date scientific information relevant to health effects associated with exposure to radiation; (b) identify human health effects associated with exposure to radiation, identify areas where knowledge is incomplete, and attempt to increase understanding by both stimulating and conducting research necessary to fill these gaps; (c) develop and provide risk assessments for and participate with other Bureau components in regulatory, educational, and use control activities; and (d) interact with national and international public and private organizations to disseminate risk information, promote radiation protection, and communicate common goals. In addition, the Ionizing Radiation and Statistics Branch will provide statistical support for the risk

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assessment activities of the Division and statistical support to other components of the Bureau.

For additional information on the reorganization or the staffing of the new branches, please contact Dr. Kenneth Krell, Bureau of Radiological Health (HFX-100), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2356.

BRH To Cosponsor International Symposium on Short-Lived Radionuclides

The Food and Drug Administration's Bureau of Radiological Health and the Department of Energy's Office of Health and Environmental Research will cosponsor an International Symposium on the Developing Role of Short-Lived Radionuclides in Nuclear Medical Practice, May 3-5, 1982, at the Pan American Health Organization Building in Washington, D.C. Other cosponsors of the symposium are the American College of Nuclear Physicians, the Society of Nuclear Medicine, and the Pan American Health Organization.

The symposium is a followup meeting to the May 1975 Bureau-sponsored conference in Rockville, Maryland, on Applications of Iodine-123 in Nuclear Medicine (BRH Bulletin, May 27, 1975). The objective of this year's meeting is to define the current role and state of the art in the development of short-lived radionuclides (with half-lives of 2 hours to 3 days) in current nuclear medical practice. Special emphasis will be placed on radionuclides with general-purpose labeling capability, the need for high-purity iodine-123, and facilities and techniques for production of short-lived radionuclides within the government or the private sector. The meeting will serve as a forum for concerned groups to explore and coordinate potentials for a dependable commercial supply of short-lived radionuclides through the establishment of a network of production accelerators analagous to a power network grid.

On the first day of the program, the speakers will review the history of short-lived radionuclide development, discuss the role of sponsoring agencies, and present an overview of current national and international uses and potentials.

Topics to be addressed on the second day include present and potential production in government, noncommercial, and commercial facilities, and uses of and labeling with short-lived radionuclides with emphasis on iodine-123. An evening session has been scheduled for the presentation of additional submitted papers.

The meeting will conclude with panel discussions on short-lived radionuclide production, distribution, and labeling applications for use in nuclear medicine clinical practice, and a summary of present and future uses of short-lived radionuclides.

The registration fee for the symposium is $60. To preregister, please send a check payable to the American College of Nuclear Physicians to

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the American College of Nuclear Physicians, 1101 Connecticut Avenue, Suite 700, Washington, D. C. 20036.

Information on the meeting may also be obtained from Dr. Peter Paras, Bureau of Radiological Health (HFX-4), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-6220.

Six New Members Appointed to TEPRSSC

Six new members have been appointed to serve 4-year terms on the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). The new members began their terms in January 1982. They are replacing members who completed their appointments in December 1981.

The new members are Mr. David E. Janes, Chief, Nonionizing Radiation Surveillance Branch, Office of Radiation Programs, Environmental Protection Agency; Dr. Thomas F. Budinger, Professor of Bioinstrumentation and Electrical Engineering, Donner Laboratory, University of California; Ms. Janice L. Gordon, Safety and Health Coordinator, International Union of Electrical, Radio, and Machine Workers; Mr. Maurice E. Neuweg, Deputy Director, Office of Radiation Safety, Illinois Department of Nuclear Safety; Mr. David H. Sliney, Chief, Laser/Microwave Branch, U. S. Army Environmental Hygiene Agency; and Dr. Max M. Weiss, Director, Radiation Protection Group, Industrial Hygiene and Safety Administration Department, Bell Laboratories.

The appointments were made by the Commissioner of the Food and Drug Administration, Dr. Arthur Hull Hayes, Jr.

The primary responsibility of the Committee, as mandated by the Radiation Control for Health and Safety Act of 1968, is to advise the Secretary of the Department on the need for and development of federal performance standards for radiation-producing electronic products. The Secretary is required to consult the Committee before issuing or modifying any such standards. The Commissioner of the Food and Drug Administration has been delegated this responsibility.

The Act states that the Committee shall be comprised of 15 members, including five from government (state and federal), five from the affected industries, and five from the general public--one of whom must be a representative of organized labor. The law requires that each member be "technically qualified by training or experience in one or more fields of science or engineering applicable to electronic product radiation safety." Selection of members is made after consultation with public and private agencies concerned with radiological health and safety as well as with representatives of industry, labor, and academia, and trade, professional, and public interest groups.

TEPRSSC members who completed their tenure last year were Dr. Edwin L. Carstensen, Mr. Kenneth R. Edwards, Mr. Elmer H. Eisenhower,

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Mr. Charles M. Hardin (chairperson), Col. Thomas L. Pitchford, and Mr. Stanley D. Savic. Members whose terms are continuing are Dr. Valerie A. Brookeman, Mr. Cazamer L. Crouch, Dr. William R. Ingles, Mr. Howard W. Johnson, Dr. Wende W. Logan, Ms. Mary E. Moore, Mr. Gerald S. Parker (chairperson), Mr. Gerald A. Richardson, and Ms. Goldie B. Watkins.

The Executive Secretary of TEPRSSC is Dr. Zory R. Glaser of FDA's Bureau of Radiological Health.

Corrective Action Plans

During March 1982, the Bureau of Radiological Health approved one manufacturer's corrective action plan for products found in noncompliance with performance standards issued under the Radiation Control for Health and Safety Act. The products involved are:

1109 GX-550 "Galaxie" x-ray controls, approximately 600 of which are in fluoroscopic use and some 509 of which are used for radiography only, manufactured by Picker International of Highland Heights, Ohio. The units involved are model 851 (serial numbers 509-1006), model 851A (serial numbers 1150-1311), and model 851B (serial numbers 105-448). Based on summaries of field test data, the Bureau declared the Galaxie x-ray controls to be in noncompliance with the entrance exposure rate requirements of the federal performance standard for diagnostic x-ray systems. Picker has agreed to modify the controls and to recalibrate them at no cost to users. The firm's corrective action plan consists of: (1) notifying users of the noncompliance, (2) for units used for radiography only, attaching a label to the unit so that future upgrades of that unit to a fluoroscopic mode would include installation of a modification kit, (3) for fluoroscopic units, adding compensatory circuitry to assure proper entrance exposure rates over a 5-percent line voltage range, and (4) recalibrating all fluoroscopic controls with a revised set of instructions.

New Bureau Publications

The following publications are available for purchase from either the Government Printing Office or the National Technical Information Service, as indicated in the parentheses following the citation.

"Bureau of Radiological Health Publications Subject Index," (FDA 82-8070), compiled by the Technical Information Staff, Office of Management and Systems. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-160250, $6.00 per copy, $4.00 for microfiche.)

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"CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1980 - Health Effects of Prenatal and Postnatal Whole-Body Exposure to Ionizing Radiation in the Beagle Dog" (FDA 82-8042), prepared by the Collaborative Radiological Health Laboratory, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, in collaboration with the Division of Biological Effects, under contracts FDA 72-302 and 223-76-6002. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-177817, $13.50 per copy, $4.00 for microfiche.)

"Radiation Safety in Nuclear Medicine: A Practical Guide" (FDA 82-8180), edited by Vincent J. Sodd, Nuclear Medicine Laboratory, Division of Electronic Products. (Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402; Stock No. 017-015-00203-9, $4.75 per copy.)

"Report on Classroom Use of Sodium Vapor Lamps" (FDA 82-8183), Loren F. Mills and F. Alan Andersen, Division of Biological Effects. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-169517, $6.00 per copy, $4.00 for microfiche.)

"Sourcebook of Educational Materials for Dental Radiology" (FDA 82-8182), compiled by Sheila Richard and Marion Torchia, Capital Systems Group, Inc., and Lireka P. Joseph, Division of Training and Medical Applications. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-165580, $9.00 per copy, $4.00 for microfiche.)

May 1982 Calendar of Events

The following is a list of May 1982 meetings of relevance to Bureau activities and the talks and exhibits to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Meeting of the American Association of Medical Dosimetrists, Philadelphia, Pennsylvania, May 10-14, 1982.

"Problem Reporting Program for Radiation Therapy Devices," Marcia S. Shane, Division of Training and Medical Applications.

Joint Meeting of the Society of Photo-Optical Instrumentation Engineers and the American Roentgen Ray Society--Application of Optical Instrumentation in Medicine X, New Orleans, Louisiana, May 12, 1982.

"The Role of the Bureau of Radiological Health in Assessment of Risks from Clinical NMR Procedures," Mary P. Anderson and T. Whit Athey,

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Division of Electronic Products, and Robert A. Phillips, Division of Compliance.

Fourteenth Annual National Conference on Radiation Control, Portland, Maine, May 23-27, 1982.

"Report on Current and Projected Federal Radiation Protection Activities," John C. Villforth, Director, Bureau of Radiological Health.

"Manitoba Rare Earth Experience," Ira P. Leggett, Division of Compliance.

"RF Sealers," William A. Herman, Division of Electronic Products.

"Field Evaluation of Nuclear Medicine Xenon Traps," Richard van Tuinen, Division of Electronic Products.

"FDA Guidance on KI," Gordon C. Johnson, Office of Health Affairs.

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BRH BULLETIN

Bureau of Radiological Health

ORIGINAL

Monday, May 17, 1982 • Volume XVI, No. 5

In this issue:

- Microwave Calibration Intercomparisons
- Radiation Therapy Workshop
- Dental Radiology Sourcebook
- Report on RF Survey Instrument Performance
- Corrective Action Plan
- New Bureau Publications
- June 1982 Calendar

Bureau Initiates Microwave Calibration Intercomparison Program

The Bureau of Radiological Health recently initiated a calibration intercomparison program with the National Bureau of Standards (NBS) in Boulder, Colorado, for microwave survey instruments operating at 2.45 gigahertz. The impetus for the program was the Bureau's concern for consistency within the federal government in the calibration of instruments used for nonionizing radiation measurements. Furthermore, because microwave oven manufacturers are investigating the use of automated oven leakage measurement systems for determining compliance with the federal microwave oven performance standard, it has become more important than ever to minimize errors caused by calibration. The manufacturers use the very accurate calibration facilities of NBS, so coordination with NBS is essential to the Bureau's microwave oven compliance program.

The Bureau also has begun an international intercomparison program with the Japan Machinery and Metals Inspection Institute (JMI) and the Canadian Radiation Protection Bureau. JMI is similar to NBS and provides Japanese microwave oven manufacturers with calibration standards. It follows that close coordination between the Bureau and JMI will have an impact on compliance measurements of Japanese microwave ovens. The intercomparisons made thus far indicate good correlation between survey instrument calibrations performed in the U.S., Japan, and Canada.

In addition to the direct impact of these intercomparisons on microwave oven compliance testing, they are also important in monitoring the performance of microwave diathermy equipment. Microwave diathermy safety is determined by measuring leakage or stray radiation, and the accuracy of the determination can be improved by reducing the measurement uncertainties. Such efforts aid manufacturers in designing safer devices and assist users in identifying those that are safe.

The importance of accurate microwave diathermy measurements is demonstrated in a recent paper published in the British journal "Physics in Medicine and Biology" concerning the effectiveness of various types of microwave diathermy applicators

(BRH Bulletin, December 14, 1981). The paper describes a Bureau study in which precisely calibrated survey instruments were used to map the radiated energy fields and to measure leakage and scatter radiation around the applicators. The same instruments aided in the design of safer, more effective applicators.

In the past the Bureau participated in an international microwave calibration intercomparison program developed by the Australian standards laboratory (CSIRO). That program involved calibration of the same instruments by several international standards laboratories. Among the other participants were NBS and government laboratories of Italy, Sweden, and Great Britain. The CSIRO program, however, was a one-time effort rather than a continuing one such as the Bureau's present program with JMI and Canada.

For additional information about the program, please contact Donald Witters, Bureau of Radiological Health (HFX-240), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3840.

Topical Workshop on Radiation Therapy Presented at Regional Meetings

At the Regional Radiological Health Training Conferences this year, the Radiation Therapy Branch of the Bureau of Radiological Health's Division of Training and Medical Applications conducted the second Bureau topical workshop for state radiation control program directors. The workshop, "Radiation Therapy - Medical Linear Accelerators," was designed to orient the program directors and other state personnel to the clinical and safety issues of radiation therapy and to introduce them to the theory and operation of medical linear accelerators. The first Bureau topical workshop was presented last year and dealt with communication with the press and the public.

The radiation therapy workshop and accompanying workbook addressed radiation oncology, clinical personnel, steps in treatment, the importance of accuracy, and equipment problems that have been reported through the Problem Reporting Program for Radiation Therapy Devices (PRP) coordinated by the United States Pharmacopeia. An overview of both treatment and treatment planning equipment was presented, and the use of cobalt-60 for radiation therapy was discussed. The main emphasis, however, was on the theory and operation of linear accelerators in radiation therapy. Other topics addressed included the items to be considered in the commissioning of a medical linac, the need for quality assurance procedures, and elements of radiation safety surveys in radiation therapy facilities.

The workshop increased the program directors' awareness of the many facets of radiation therapy that must be considered in planning a radiation control program. The directors will receive further assistance in this area from a new task force on radiation therapy established by the Conference of Radiation Control Program Directors and chaired by Robert M. Quillin, Radiological Health Program Director from Ohio.

Several Bureau-produced training materials were used during the workshop. These included:

- A videotape from the "Topics in Radiation Therapy" series titled "Progress and Costs in Radiation Therapy" (BRH Bulletin, June 8, 1981). Videotapes in this

series are available in 3/4-inch format and may be borrowed on a short-term free-loan basis from the Training Resources Center, Bureau of Radiological Health (HFX-73), 5600 Fishers Lane, Rockville, Maryland 20857.

• A three-part videotape titled "Linear Accelerators in Radiation Therapy: Theory and Operation" (BRH Bulletin, March 15, 1982). This videotape may be purchased in 1/2-inch and 3/4-inch formats from the National Audiovisual Center. For ordering information or to borrow the program (in 3/4-inch format) on a short-term free-loan basis, please contact the Bureau's Training Resources Center at the above address.

• A report titled "A Primer on Theory and Operation of Linear Accelerators in Radiation Therapy." This report may be purchased from the Government Printing Office, Washington, D.C. 20402. The price is $4.25 per copy, and the stock number is 017-015-00204-7 (BRH Bulletin, March 15, 1982).

The radiation therapy workbook used in the workshop has not been published.

Dental Radiology Sourcebook Available

The Bureau of Radiological Health has prepared a new publication that presents an annotated listing of educational materials in dental radiology designed to assist persons concerned with the education of dental and dental auxiliary students and with the continuing education of dental practitioners. The document, "Sourcebook of Educational Materials for Dental Radiology" (FDA 82-8182), was compiled by surveying dental schools, audiovisual producers, textbook publishers, professional associations, and companies involved in the production of dental radiology materials. To keep the information current, the Sourcebook lists printed matter published after 1975 and audiovisuals produced after 1973.

The Sourcebook is divided into various subparts that provide background information on specific as well as on more general areas that have a bearing on the practice of dental radiology. Entries have been organized into a number of categories categories including "Scientific Background," "Radiographic Techniques," "Workbooks and Self Teaching Manuals," and "Film and Film Processing." One appendix to the document provides publishers' addresses, while another contains guidelines issued by the American Association of Dental Schools for dental auxiliary radiology curriculum objectives.

The Sourcebook may be purchased from the National Technical Information Service, Springfield, Virginia 22161. The Accession Number is PB 82-165580, and the price is $9.00 per paper copy and $4.00 for microfiche.

For further information about the Sourcebook, please contact Dr. Lireka Joseph, Bureau of Radiological Health (HFX-76), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-4600.

Report Published on Performance of RF Survey Instruments

The Bureau of Radiological Health has published a report that describes the test methods and results of a study of three commercially available radiofrequency

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(RF) survey instruments and one one-of-a-kind device. These instruments are designed to measure the strength of the RF fields emitted during the operation of dielectric heaters, shortwave diathermy units, and other products that emit RF energy. They were evaluated over the frequency range from 10 to 100 megahertz with emphasis on 27.12 megahertz, an ISM frequency at which many of the RF products operate.

Two of the instruments evaluated are used for electric (E) field measurements--the Instruments for Industry RHM-2 isotropic E-field radiation hazard monitor and the Instruments for Industry EFS-1 single-antenna electric field strength meter; and two are used for magnetic (H) field measurements--the Southwestern Research Institute SwRI one-of-a-kind isotropic H-field meter and the Narda Microwave Corporation 8607 system which consists of a Narda 8633 isotropic H-field probe and a Narda 8616 readout. They were tested for linearity, calibration accuracy, amplitude modulation response, directivity, antenna patterns, temperature response, drift and noise, radiofrequency interference, and polarization response.

One of the discoveries made during this series of tests was that an instrument may not be suitable for survey use even though it works well in an ideal exposure situation where only the probe sensor is exposed to RF radiation. It was concluded, however, that the instruments evaluated are capable of functioning properly and yielding reliable field measurements under most conditions of normal use.

Several additional instruments designed for use in this frequency range are commercially available and are currently being evaluated by the Bureau. The results of these tests will be reported in future publications.

The report, "Performance Evaluation of RF Electric and Magnetic Field Measuring Instruments" (FDA 82-8158), is available only from the National Technical Information Service, Springfield, Virginia 22161. The Accession Number is PB 82-195009, and the price is $7.50 per paper copy and $4.00 for microfiche.

Corrective Action Plans

During April 1982, the Bureau of Radiological Health approved one manufacturer's corrective action plan for products found in noncompliance with a performance standard issued under the Radiation Control for Health and Safety Act. The products involved are:

- 8 TEA-Co-2 laser products, models DD-250 and DD-300, manufactured by Gen-Tec, Incorporated, Quebec, Canada. The units failed to comply with the federal laser product performance standard because the remote control connectors were inadequate, the logotype and aperture labels were incomplete, the user and service manuals did not include reproductions of and information about the location of the warning labels, and the logotype was omitted in the sales literature. The firm's corrective action plan consists of notifying users of the noncompliance and providing them with a diagram and instructions on how to connect the local and remote control shutter switches in series, modified logotype and aperture labels, inserts for the user manual containing reproductions of the required labels, instructions for proper placement and attachment of the labels to the units, and a completion form to be returned to the manufacturer following the corrections.

New Bureau Publications

The following publications are available for purchase from the National Technical Information Service, as indicated in the parentheses following the citation.

"Performance Evaluation of RF Electric and Magnetic Field Measuring Instruments" (FDA 82-8158), Billy C. W. Nesmith and Paul S. Ruggera, Division of Electronic Products. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-195009, $7.50 per copy, $4.00 for microfiche.)

"Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components" (FDA 82-8184), originally compiled by the Division of Compliance in February 1973 and revised in January 198[illegible]. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-185158, $10.50 per copy, $4.00 for microfiche.)

June 1982 Calendar of Events

The following is a list of June 1982 meetings of relevance to Bureau activities and the talks and exhibits to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Seventh International Symposium on Ultrasonic Imaging and Tissue Characterization, Gaithersburg, Maryland, June 6.

"Low Contrast Detectability and Contrast/Detail Analysis in Medical Ultrasound," Stephen W. Smith and Robert F. Wagner, Division of Electronic Products; John M. Sandrik, General Electric Company; and Hector Lopez, Division of Training and Medical Applications.

"Second Order Statistics for Speckle in Ultrasound B-Mode Scans of a Uniform Scattering Phantom," Robert F. Wagner and Stephen W. Smith, Division of Electronic Products; John M. Sandrik, General Electric Company; and Hector Lopez, Division of Training and Medical Applications.

National Parent Teachers Convention, Nashville, Tennessee, June 6 - 8.

Poster Presentation: "Mercury Vapor and Metal Halide Lamps: Control the Hazards in Your School," Joyce N. Rollings, Division of Training and Medical Applications.

American Industrial Hygiene Association Conference, Cincinnati, Ohio, June 6 - 11.

"Occupational Exposure to Ethylene Oxide in Selected North Carolina Hospitals," Greg P. Lathan, General Electric Company, and Zory R. Glaser, Division of Compliance. (To be presented by Greg P. Lathan.)

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Society of Radiological Protection--Third International Symposium: Radiation Protection, Advances in Theory and Practice--Inverness, Scotland, June 6 - 11.

"Tissue Doses in Diagnostic Radiology: Radiation Risk Assessment for the Patient," Marvin Rosenstein, Office of the Bureau Director.

29th Annual Meeting of the Society of Nuclear Medicine, Miami Beach, Florida, June 15 - 18.

"Chemistry and Preparation of the Potential Myocardial Imaging Agent Tc-99m DMPE," E. Deutsch, K. Libson, J. L. Vanderheyden, and D. L. Nosco, University of Cincinnati, and Vincent J. Sodd and Hiroshi Nishiyama, Division of Electronic Products.

"Monitoring of Xenon-133 Charcoal Trap Efficiency Using a GM Survey Instrument," Laurence W. Grossman and Richard J. Van Tuinen, Division of Electronic Products, and James G. Kereiakes, University of Cincinnati.

"Non-Visualization of the Biliary Tract and Intestine in Tc-99m IDA Imaging," Hiroshi Nishiyama, Division of Electronic Products, and J. Mantil, D. Volarich, and M. Gelfand, University of Cincinnati.

"Tc-99m DMPE as a Functional Myocardial Imaging Agent," Hiroshi Nishiyama and Vincent J. Sodd, Division of Electronic Products, and S. J. Lukes, E. A. Deutsch, R. J. Adolph, K. Libson, M. C. Gerson, J. L. Vanderheyden, M. Gable, and E. L. Saenger, University of Cincinnati.

"Tc-99m DMPE as a Myocardial Imaging Agent: Organ Distribution and Dosimetry in the Rat," Vincent J. Sodd, Kenneth L. Scholz, Laurence W. Grossman, Donald L. Fortman, Philip J. Robbins, and Hiroshi Nishiyama, Division of Electronic Products, and E. Deutsch, R. J. Adolph, and K. Libson, University of Cincinnati.

"Tc-99m DMPE as a Resting Myocardial Imaging Agent," Hiroshi Nishiyama and Vincent J. Sodd, Divsion of Electronic Products, and Steven J. Lukes, E. A. Deutsch, R. J. Adolph, K. Libson, M. Gabel, M. C. Gerson, J. L. Vanderheyden, and E. L. Saenger, University of Cincinnati.

Annual Meeting of the Society for Epidemiologic Research, Cincinnati, Ohio, June 16 - 18.

"Effects of Sonic Radiation on Growth and Development," Roscoe M. Moore, Jr., M. Kay Barrick, and Peggy M. Hamilton, Division of Biological Effects.

"Followup Study of Persons Who Had I-131 and Other Diagnostic Procedures During Childhood," Peggy M. Hamilton, James Logue, Richard P. Chiacchierini, Frank E. Lundin, Jr., Division of Biological Effects, and B. Harris, NTS Research Corporation.

10th Annual Meeting of the American Society for Photobiology, Vancouver, British Columbia, Canada, June 27 - July 2.

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"Effects of In Vivo Exposure to Special Blue Light on Neonatal Blood Plasma Free Amino Acids," Richard P. Felten, and Anthony Lamanna, Division of Biological Effects.

Health Physics Society Annual Meeting, Las Vegas, Nevada, June 27 - July 1.

"Evaluation of the External Radiation Exposure Dosimetry of Airborne Materials Containing Fluorine-18, Oxygen-15, Nitrogen-13, and Carbon-11," Harley V. Piltingsrud and Gerald L. Gels, Division of Electronic Products.

"Issues Concerning the Use of Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Accident," Bernard Shleien, Office of Health Affairs, and J. A. Halperin, J. M. Bilstad, S. Kahana, and E. V. Dutra, Jr., Bureau of Drugs.

"A Sensitometric Technique for Evaluation of Processing of Medical X-Ray Film," Orhan H. Suleiman and Charles K. Showalter, Division of Training and Medical Applications.

Poster Presentation: "A Sensitometric Technique for the Evaluation of Processing (STEP)," Orhan H. Suleiman and Charles K. Showalter, Division of Training and Medical Applications.

Fourth Annual Meeting of the Bioelectromagnetics Society, Los Angeles, California, June 28 - July 2.

"An Analysis of Safety Aspects of Nuclear Magnetic Resonance (NMR) Medical Imaging Systems," T. Whit Athey, Division of Electronic Products.

"Changes in Metaphase Counts, Meiotic Translocations, and Univalency Following 2.45 GHz Exposure of Male CBA Mice," E. Manikowska-Czerska, Przemyslaw Czerski, and William M. Leach, Division of Biological Effects.

"The Effect of 2450 MHz on Blood-Brain Barrier Permeability in the Mouse," John C. Monahan and Benjamin R. Fisher, Division of Biological Effects.

"Optimizing Frequency Response Characteristics of an E/H Probe," Tadeusz M. Babij and Howard I. Bassen, Division of Electronic Products.

"Pitfalls of Certain Plane Wave Exposures of Biological Specimens," Howard I. Bassen, Division of Electronic Products.

"Power Deposition in a Head Model Exposed to Hand-Held UHF Transceivers," T. Whit Athey, Division of Electronic Products, and Robert F. Cleveland, Federal Communications Commission.

"Protective Action Guides for Human Food and Animal Feeds," Gail D. Schmidt, Office of the Bureau Director, and Bernard Shleien, Office of Health Affairs.

"A Status Report on and a Comparison of United States and International RF/Microwave Radiation Standards/Guidelines--Development Activities," Zory R. Glaser, Division of Compliance; Robert F. Cleveland, Federal

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Communications Commission; and Przemyslaw Czerski, Division of Biological Effects.

Poster Presentation: "A Comparison of E-Field Energy Deposition in Simulated Eyes Located in Dielectrically Filled Skulls of the Rabbit, Guinea Pig, and Human," Esther S. Ferri and William P. Edwards, Division of Biological Effects.

Poster Presentation: "Stages in Development of a Microwave Cataract in the Rabbit Eye Viewed in Color Stereophotographs," Russell L. Carpenter, Division of Biological Effects.

Gordon Conference: Lasers in Medicine and Biology, Meriden, New Hampshire, June 28 - July 2.

"A New Laser Power/Energy Calorimeter," Robert J. Landry, Division of Electronic Products.

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BRH BULLETIN
bureau of radiological health

JUN 12 1984

Monday June 21, 1982 • Volume XVI, No. 6

In this issue:

- WHO/IRPA Nonionizing Radiation Protection Activities
- Report on 14th Annual Radiation Control Conference
- DTMA Reorganization
- RFP on Optimization of Chest Radiography
- Report on X-Ray Screen-Film Imaging Characteristics
- New Officers of Radiation Control Conference
- Rad Health Reunion Announcement
- New Bureau Publication
- July 1982 Calendar

Bureau Continues International Nonionizing Radiation Protection Activities

The Bureau of Radiological Health continued its participation in international nonionizing radiation protection activities during the past month when several staff members attended meetings to finalize two draft environmental health criteria documents--one on ultrasound and one on lasers and optical radiation. The documents are being prepared through the joint efforts of the World Health Organization (WHO) and the International Nonionizing Radiation Committee (INIRC) of the International Radiation Protection Association (IRPA). The final documents will be the most comprehensive examination to date of the state of the art of ultrasound and lasers. They will address such topics as physical characteristics and measurements, applications, and biological effects.

For the past several years WHO has been developing and publishing a series of environmental health criteria documents for various chemical and physical agents. Under an agreement between WHO and IRPA, IRPA has been providing the scientific expertise needed to develop the documents on nonionizing radiation. These documents, which contain the collective views of international groups of experts, are intended to serve as the basis for developing recommended exposure limits.

The Bureau has been providing input to this effort through active participation in the work of IRPA/INIRC. It also has served as the WHO Collaborating Centre for Nonionizing Radiation since 1974.

Three meetings relating to the development of the criteria documents and recommended exposure limits for nonionizing radiation were held during the past month. On May 25-29, IRPA/INIRC met in Paris to discuss proposed exposure limits for various nonionizing radiation ranges and the development of new criteria documents. This meeting was attended by Dr. Przemyslaw Czerski, a committee member and visiting scientist with the Bureau's Division of Biological Effects.

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On June 1-6, a joint WHO/IRPA task group of experts from around the world met in Paris to prepare the final version of the environmental health criteria document on lasers and optical radiation. Dr. Czerski and Robert J. Landry of the Bureau's Division of Electronic Products participated in the group's deliberations.

On June 7-12, another joint WHO/IRPA task group of international experts met in Geneva to finalize the environmental health criteria document on ultrasound. This meeting was attended by Dr. Melvin Stratmeyer of the Bureau's Division of Biological Effects and Dr. Harold Stewart of the Bureau's Division of Electronic Products, who has acted as coordinator for prior drafts of the document and for reviews of those drafts.

It is expected that both the ultrasound and the laser environmental health criteria documents will be published by the end of 1982. Once the documents have been published, they will be available from the WHO Publications Centre, 49 Sheridan Avenue, Albany, New York 12210.

Radiation Control Program Directors Meet in Portland, Maine

Representatives of local, state, and federal radiation control agencies, professional organizations, industry, and others with an interest in radiation protection met from May 24 through 27, 1982, at the Fourteenth Annual National Conference on Radiation Control in Portland, Maine. The Conference was hosted by the Radiological Health Program of the Maine Department of Human Services and was sponsored by the Conference of Radiation Control Program Directors, Inc. (CRCPD), FDA's Bureau of Radiological Health, the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Federal Emergency Management Agency. The American College of Radiology (ACR) continued its support of the annual meeting by sponsoring a half-day session of the program.

The Conference, which focused on priorities in radiation protection, began on Monday with a welcome from Wallace Hinckley of Maine, the meeting host, and other Maine officials. John R. Stanton, Conference chairman, then reviewed for attendees the Conference's major activities since the 1981 meeting. Next, Robert Bernstein, M.D., Commissioner of the Texas Department of Health, gave the keynote address for the meeting. Dr. Bernstein's message to the Conference stressed the need to place radiation protection activities into proper perspective and to do a better job of educating the public about radiation. Following Dr. Bernstein's talk, Joseph P. Hile, FDA's Associate Commissioner for Regulatory Affairs, briefed the attendees on legislative and Administration initiatives related to regulatory reform, and Thomas Aschenbrener of the Health Resources Administration of HHS presented a status report on the Consumer-Patient Radiation Health Act of 1981. Reports by the sponsoring federal agencies on current and projected radiation protection activities concluded the day's formal session.

Tuesday morning's program addressed the public's perception of radiation from the viewpoints of the medical community, the news media, and the radiation control program directors. Methods of disseminating information to the public were discussed, and a videotape on effective communication was presented. During Tuesday afternoon's session, which was cosponsored by the ACR, discussions

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focused on the problem of fees to support state radiation control programs, user credentialing, and new technology in diagnostic imaging.

On Wednesday morning, discussions centered on what constitutes a comprehensive state radiation control program and what would be worth saving if budgets were drastically reduced. Four program directors then described how priorities are really set in their states. Other topics addressed on Wednesday included recent regulatory and voluntary initiatives in the nonionizing radiation area, quality assurance programs for personnel dosimetry, and the feasibility of a "de minimus" approach.

The final day's session was devoted to emergency planning and problems associated with low-level waste and naturally occurring radioactive materials. The highlight of this session was a panel discussion of potassium iodide distribution, an issue of concern to many state and federal agencies.

The Conference proceedings are being prepared for publication by the CRCPD.

Division of Training and Medical Applications Reorganized

The Bureau of Radiological Health's Division of Training and Medical Applications has been reorganized to reflect the redirection of its efforts over the past few years. The new structure emphasizes the Division's assistance to and cooperation with state and federal medical radiation programs as well as the development of programs and procedures to reduce unnecessary radiation exposure.

The new structure includes six branches: Federal-State Programs, Medical, Technical Development, Radiation Therapy, Examination Trends Analysis, and Training Support. The Office of the Director now includes an Assistant Director for Medical Devices and the Program Management Staff.

The Medical Branch and the Radiation Therapy Branch have been retained from the previous organization. The Training Support Branch is the former Program Support Branch less the Program Management Staff. The three new branches--Federal-State Programs, Technical Development, and Examination Trends--replace the former Quality Assurance, Nuclear Medicine, and Analysis and Evaluation Branches.

The Federal-State Programs Branch will continue the Division's active interface with federal and state radiation control programs and will administer such cooperative programs as NEXT, BENT, DENT, and other quality assurance applications. The Technical Development Branch will continue to develop quality assurance and exposure reduction programs for conventional radiography, digital imaging, and nuclear medicine, and will interface with the medical physics community. The Examination Trends Analysis Branch will be responsible for the Radiation Experience Data (RED) program and future national surveys on population exposure.

The Medical Branch will continue to interface with the professions on patient selection and examination efficacy issues, consumer education, and technologist

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credentialing. The Radiation Therapy Branch will continue to interface with the therapy community in the areas of education, quality assurance, and equipment problems. The Training Support Branch will continue to coordinate development of the Bureau's educational and training programs and to administer the Training Resources Center and the National Radiological Health Information Network.

For additional information on the reorganization or the staffing of the branches, please contact William S. Properzio, Director, Division of Training and Medical Applications, Bureau of Radiological Health (HFX-70), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2845.

Proposals Sought for Contract on Optimization of Chest Radiography

The Bureau of Radiological Health is seeking proposals for a contract titled "Optimization of Chest Radiography." The project requires the development of a mathematical model capable of predicting physical imaging performance in chest radiography and use of the model to determine optimum designs for chest radiography systems.

Among the parameters the contractor must consider in developing the model are anode heat limits, exposure time, focal spot size, high voltage amplitude (kVp) and waveform, x-ray beam filtration, system geometry, scattered radiation and techniques for its suppression, and image receptor characteristics. Objects to be imaged include small calcifications (1 millimeter) and soft tissue objects (from 1 millimeter to 1 centimeter) with composition similar to normal tissue, embedded in or on a matrix of air, soft tissue, and bone equivalents simulating the human chest; the composition and thickness of the background matrix components are to be variable. Criteria to be used in evaluating the model include contrast (radiation field and final image), signal-to-noise ratio and signal-to-background ratio (where background refers to the "signal" from elements of the chest matrix), x-ray tube heat loading, system energy efficiency index (energy deposited in the image receptor divided by x-ray tube heat loading), and patient dose.

Copies of the Request for Proposal (RFP No. 223-82-6010) are available from the Food and Drug Administration (HFA-511), 5600 Fishers Lane, Room 12A-17, Rockville, Maryland 20857. Inquiries regarding the work to be performed or the mechanism for submitting a proposal should be directed to Mrs. Jacquelyn C. Carey of FDA's Negotiated Contracts Branch at the above address, telephone (301) 443-4420. The deadline for submission of proposals is July 12, 1982.

Report Published on X-Ray Screen-Film Imaging Characteristics

The Bureau of Radiological Health has published a report that describes methods of measuring the fundamental imaging characteristics of radiographic screen-film combinations. The report also presents the results of imaging characteristic measurements performed on a selection of new and conventional screen-film systems. This work was the result of a collaborative effort between the Medical Physics Branch of the Bureau's Division of Electronic Products and the University of Chicago's Kurt Rossmann Laboratories for Radiologic Image Research.

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The report is divided into two parts. Part 1 describes the methods and results of the interlaboratory comparison of measurements of sensitometry, modulation transfer functions, and Wiener spectra of three screen-film systems. Part 2 presents data generated at the Rossmann Laboratories on sensitivity, sensitometry, resolution, and noise characteristics of new screen-film systems. These data will be useful in the proper selection of systems for various diagnostic examinations.

The first part of the report will be of general interest to those seeking information on the theory and practice of fundamental imaging measurements of screen-film systems and of particular interest to those with a serious commitment to the measurement of these quantities. The second part will be of value to those seeking imaging data as input to research on diagnostic radiologic imaging systems and to those attempting to develop quantitative, physical comparisons of imaging systems.

The report, "MTF's and Wiener Spectra of Radiographic Screen-Film Systems" (FDA 82-8187), may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. The stock number is 017-015-00205-5, and the price is $5.50 per copy.

The development of additional information to facilitate the use of these data by the clinical community in the evaluation of screen-film combinations for particular diagnostic tasks is under consideration. Discussions of this matter have been initiated with the American College of Radiologists and the American Association of Physicists in Medicine. Anyone interested in participating in or contributing to the discussions should contact Robert Jennings, Bureau of Radiological Health (HFX-250), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5020.

Shealy Assumes Leadership of Radiation Control Program Directors Conference

Heyward G. Shealy, Chief of the Bureau of Radiological Health of the South Carolina Department of Health and Environmental Control, is the new chairman of the Conference of Radiation Control Program Directors, Inc. Shealy's appointment to the post was confirmed during the Fourteenth Annual National Conference on Radiation Control in Portland Maine. He had been named chairman-elect at the 1981 meeting in recognition of his contributions to the Conference and his leadership abilities.

The new chairman-elect is A. J. Hazle, Director of the Division of Radiation and Hazardous Waste Control of the Colorado Department of Health. Other new members elected to the Board of Directors are Aubrey Godwin, Director of the Division of Radiological Health of the Alabama Department of Public Health, who has assumed the duties of treasurer, and Charles F. Tedford, Executive Director of the Arizona Radiation Regulatory Agency, who will serve on the Board as member-at-large.

Other members of the Executive Board include John R. Stanton, Chief of the Bureau of Environmental Health of the New Hampshire Department of Health and Welfare, who is the immediate past-chairman, and Lawrence J. McDonnell, Chief of the Wisconsin Radiation Protection Section, and Eddie S. Fuente, Director of the Mississippi Division of Radiological Health, who are members-at-large.

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Radiological Health Reunion Set for October

The Radiological Health Alumni Association has planned a get-together on the first weekend in October 1982. On Friday afternoon, October 1, there will be an open house at Bureau of Radiological Health headquarters in Rockville; on Saturday evening, October 2, there will be a banquet at the Washingtonian Motel in Gaithersburg; and on Sunday afternoon, October 3, there will be a picnic at Montrose Park in Rockville.

Present and former Bureau staff members and consultants are invited. Invitations have been sent to individuals whose addresses are known. Anyone who should have received an invitation but has not should contact Edna Reffit, Bureau of Radiological Health (HFX-5), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5323.

The organizers are collecting historical information to display at the reunion and would particularly like to obtain memorabilia such as photographs, instruments, and documents pertinent to past radiological health activities. Anyone who has such material to contribute should contact Lois Miller, Bureau of Radiological Health (HFX-77), at the above address, telephone (301) 443-3446.

New Bureau Publication

The following publication is available for purchase from the U.S. Government Printing Office, as indicated in the parentheses following the citation.

> "MTF's and Wiener Spectra of Radiographic Screen-Film Systems" (FDA 82-8187), Kunio Doi, Gunnila Holje, Leh-Nien Loo, and Heang-Ping Chan, University of Chicago, and John M. Sandrik, Robert J. Jennings, and Robert F. Wagner, Division of Electronic Products. (Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; Stock No. 017-015-00205-5, $5.50 per copy.)

July 1982 Calendar of Events

The following is a list of July 1982 meetings of relevance to Bureau activities and the talks to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

10th Annual Meeting of the Society for Photobiology, Vancouver, British Columbia, June 28 - July 2.

> "Ultraviolet-Induced Modulation of Immune Function: Effects on Macrophage Chemotaxis, Phagocytosis, and Interferon Production," Kiki B. Hellman and Amparo G. Strickland, Division of Biological Effects, and Arnold K. Fowler, National Cancer Institute.

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Annual Meeting of the American Society of Radiologic Technologists, New New Orleans, Louisiana, July 3 - 8.

"Legal Aspects of Radiology Records," Walter L. Scott, Division of Training and Medical Applications.

Ohio State University, College of Dentistry, Department of Continuing Dental Education, Columbus, Ohio, July 7.

"Dental Radiology for the 80's: Radiation Safety for the Patient and the Professional: The Federal Perspective," Lireka P. Joseph, Division of Training and Medical Applications.

Meeting of the American College of Veterinary Toxicologists, Salt Lake City, Utah, July 19.

"The Effects of Sonic Radiation on Growth and Development of Animal and Human Fetuses," Roscoe M. Moore, Peggy M. Hamilton, M. Kay Barrick, and Melvin E. Stratmeyer, Division of Biological Effects.

Third Meeting of the World Federation for Ultrasound in Medicine and Biology, Brighton, England, July 26 - 30.

"Effects of In Utero Ultrasound Exposure on the Growth and Development of Mice," Melvin E. Stratmeyer, Frieda Z. Pinkavitch, Lawrence R. Simmons, and Phyllis Sternthal, Division of Biological Effects.

"Contrast-Detail Analysis of Simple and Compound B-Scans," Stephen W. Smith, Hector Lopez, and Robert F. Wagner, Division of Electronic Products.

International Microwave Power Institute Symposium, San Diego, California, July 28.

"Automated Microwave Oven Survey System: Evaluation Criteria and Procedures," Donald Witters and Daniel Schaubert, Division of Electronic Products.

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BRH BULLETIN
bureau of radiological health

Monday, July 19, 1982 • Volume XVI, No. 7

In this issue:

- Villforth Named Director of Bureau of Medical Devices
- Final Recommendations on Potassium Iodide
- New Jersey Film Processor Study
- Laser Power-Energy Meter
- Contract for Scintillation Camera QA Workshop
- US-USSR Cooperative Program on Microwave Bioeffects
- Workshop on Radiofrequency Effects
- FDA and BRH Honor Awards
- August 1982 Calendar

Villforth Named Director of Bureau of Medical Devices

John C. Villforth, Director of the Food and Drug Administration's Bureau of Radiological Health (BRH), has been appointed Director of FDA's Bureau of Medical Devices. Villforth, an assistant surgeon general of the Public Health Service, will continue to hold his present post as Director of BRH.

In announcing Villforth's appointment, HHS Secretary Richard S. Schweiker also said that a merger of the two Bureaus is planned as part of a series of steps being undertaken by FDA and the Department to streamline and improve management of the Agency.

Final Recommendations Issued on Potassium Iodide for Radiation Emergencies

The Food and Drug Administration has issued its final recommendations on administering potassium iodide to the public to help prevent thyroid injury in the event of a radiation emergency involving the release of radioactive iodine to the environment. The recommendations, which were prepared by FDA's Bureau of Radiological Health and Bureau of Drugs, will be included in radiation emergency guidance being prepared by the Federal Emergency Management Agency for use by state and local officials who may decide to distribute the drug as part of their emergency response plans.

In a radiation emergency involving the release of radioactive iodine into the environment, potassium iodide could help prevent radiation injury to the thyroid by saturating the gland with nonradioactive iodine. This blocks the thyroid from absorbing radioactive iodine from the air or contaminated water, milk, or foods, and helps prevent the development of radioiodine-induced tumors.

The recommendations suggest that state and local public health officials consider the use of potassium iodide in radiation emergencies by people who are likely to

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receive more than 25 rems to the thyroid from radioiodine released into the environment. This exposure level is slightly above the 10- to 20-rem range presented in the draft recommendations issued in June 1981 (BRH Bulletin, July 13, 1981). Based on review of comments received on the draft and analysis of available information, the Agency concluded that this single value would avoid confusion over whether to use the upper or lower part of the range and still provide a prudent balance between the radiation risks from iodine-131 and the risks from short-term thyroid blocking with potassium iodide.

The thyroid-blocking dose of potassium iodide recommended by FDA is 130 milligrams per day for adults and children more than 1 year old and 65 milligrams per day for children less than 1 year old. These doses can block 90 percent of radioiodine absorption if the first dose is given a few hours before or immediately after intake of radioiodine. The drug can still block 50 percent of radioiodine absorption if the first dose is administered within 4 hours after exposure.

The recommendations also urge state and local officials who decide to include potassium iodide in their emergency response plans to establish a system for informing the public how to use the drug, how to report side effects, and how to obtain treatment for any adverse reactions. The exact rate of significant adverse reactions from short-term use in the doses recommended for thyroid blocking is not known but is expected to be low. FDA concludes in the final recommendations that "risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at projected doses of 25 rem."

The recommendations are not binding; the decision as to when and how to use potassium iodide, if at all, remains with state and local officials. While FDA provided supplies of the drug during the Three Mile Island emergency, it will not do so in similar future situations. (Last fall, the state of Tennessee distributed potassium iodide tablets to about 7,000 families living within 5 miles of the Sequoyah nuclear plant near Chattanooga.)

Although potassium iodide is a nonprescription drug, the firms approved by FDA to manufacture potassium iodide for thyroid blocking are, at this time, making the drug available only to nuclear facilities and state and local authorities.

It should be noted that the use of potassium iodide in a radiation emergency is not a panacea. It does not reduce the uptake or storage by the body of other radioactive materials, nor does it provide protection against external radiation. The recommendations stress that other protective measures such as shelter, evacuation, and respiratory protection also need to be considered.

A notice of the availability of the final recommendations was published in the June 29, 1982, Federal Register. To obtain copies of the recommendations or additional information, please contact Bernard Shleien, Bureau of Radiological Health (HFX-4), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-6220.

New Jersey Film Processor Study Shows Variations in Performance

A study of x-ray film processor operation in diagnostic radiology facilities in New Jersey has shown variations in processor performance that may be indicative of

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unnecessarily high patient exposures. The study was conducted by the Bureau of Radiological Health in cooperation with the New Jersey Bureau of Radiation Protection to compare the performance of film-chemistry-processor systems, to identify the reasons for processing differences, and to determine the impact of the processor and its associated chemistry on patient exposure.

To evaluate each processor, a control film and a film routinely used by the facility were exposed to a known amount of light from a sensitometer and developed in the processor under normal operating conditions. The developed films were then measured to determine the density and to obtain a quantitative index of processor performance called "processing speed," which varies inversely with the exposure necessary to produce a density of 1.0 above base plus fog density.

The observed performance of the film-chemistry-processor systems varied by an amount corresponding to a more than fourfold range in patient exposure, with the slower speed processors requiring higher exposures. This means that, for a given image receptor system, a patient could receive four times as much radiation exposure at one facility as at another solely because of processing differences. Reasons for this variation were failure to adhere to film manufacturers' recommended processing specifications; failure of some manufacturers to provide specific processing recommendations--a problem compounded by the numerous films, chemistries, and processors currently available; and the more traditional quality assurance problems such as incorrect temperature or improperly mixed or replenished chemistry.

A report on the study, titled "A Sensitometric Evaluation of Film-Chemistry-Processor Systems in the State of New Jersey," has been prepared and will be offered for sale by the National Technical Information Service. When ordering information becomes available, it will be published in the BRH Bulletin.

As a result of this study, the Bureau, in cooperation with the Conference of Radiation Control Program Directors, Inc., developed and began pilot testing a Sensitometric Technique for the Evaluation of Processing (STEP). The procedure, which is similar to that used in the New Jersey study, compares the processing speed measured at a facility against a reference processing speed obtained by developing films according to the manufacturer's specifications. The actual procedure takes less than 5 minutes, gives an immediate indication of processing speed, and will identify overprocessing or underprocessing. Initial results from 68 facilities evaluated by the STEP procedure indicate that the average processor is underprocessing by an amount that corresponds to an average overexposure of approximately 26 percent.

Five states are presently pilot testing the STEP procedure--Illinois, New Jersey, Pennsylvania, Ohio, and Washington. Current plans call for several more states to participate in the pilot tests. It is anticipated that the program will be available to all states that wish to participate within the next year.

Although designed for use by state radiation control programs, the STEP procedure can also be used by medical physicists, consultants, or anyone interested in the evaluation of processing. To obtain additional information on the procedure, please contact Orhan Suleiman, Bureau of Radiological Health (HFX-78), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2436.

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Bureau Acquires Laser Power-Energy Meter

A portable laser power-energy meter capable of measuring the radiation from high-energy laser products, such as those used in medicine, industry, and laser light shows, has been delivered to the Bureau of Radiological Health's Electro-Optics Branch as the result of completion of a contract with Calorimetrics, Inc., of Boulder, Colorado. The device was designed to fill the need for a portable instrument that could be used by FDA's Electro-Optics Specialists in the field for measurements to determine compliance with the laser product performance standard.

The laser power-energy meter will measure continuous-wave power up to 120 watts (2000 watts in a timed mode) and energy up to 200 joules per pulse. Multiple absorbers were supplied to allow for optimum detection of radiation in different wavelength regions.

The instrument consists of two modules--a control unit and a detector head. The control unit contains the electronics for direct readout of power in watts and energy in joules as well as for various other functions such as electrical calibration. The detector head requires no auxiliary cooling other than the fan, which is integral with the detector head.

Contract Awarded for Computer-Interfaced Scintillation Camera QA Workshop

The Food and Drug Administration has awarded a contract to the Vanderbilt University Medical School to develop and conduct a workshop that will cover quality assurance of computer-interfaced scintillation camera systems. The workshop is to be directed at the nuclear medicine technologist working with an interfaced system or preparing for such a position.

The project is part of the Bureau's effort to promote quality assurance programs in the field of nuclear medicine. Through previous work in this area, the Bureau has found that one of the most effective vehicles for this effort is the development and sponsorship of quality assurance workshops covering specific areas of interest. Four workshops have been developed to date. These were for scintillation cameras, rectilinear scanners, radiopharmaceuticals, and in vitro procedures. Each was developed in response to an identifiable educational need. The new workshop is being developed in response to the educational need created by the rapid growth and popularity of computers interfaced with scintillation cameras.

The workshop will address the growth of computer-interfaced scintillation camera systems, their differences, and the quality control procedures needed to ascertain their correct and accurate operation. The program is to be designed for an 8-hour session and is to cover the history and background of interfacing computers with scintillation cameras, the availability of computer/camera combinations, identification of parameters essential to proper operation, artifacts resulting from poor quality control testing and instrument malfunction (including visual and hardcopy examples), and appropriate hardware and software for performing quality assurance checks on all commercially available systems.

Among the materials to be developed by the contractor are a training manual for workshop participants, an administrative protocol for organizing and conducting the workshop program, audiovisual aids with a descriptive index for workshop

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speakers, protocols for carrying out experiments that will give participants hands-on experience in conducting tests, and pre- and post-workshop evaluation questionnaires.

The contractor also is to offer trial workshops in two different locations, each of which is to be attended by a minimum of 15 technologists. After the workshops have been held and evaluated, the Bureau's Division of Training and Medical Applications will organize similar workshops for presentation under the cosponsorship of the Bureau and professional organizations or appropriate state agencies.

Bureau Participating in US-USSR Cooperative Program on Microwave Bioeffects

The Bureau of Radiological Health is continuing its participation in the US-USSR cooperative program on Biological Effects of Physical Factors in the Environment under Topic 3.1, "Study of the Biological Effects of Nonionizing Microwave Radiation." A workshop on Nervous System Effects of Electromagnetic Waves was held May 25-28, 1982, at the National Institute for Environmental Health Sciences (NIEHS), Research Triangle Park, North Carolina, as part of this program. During the workshop, scientists from the Bureau, the Environmental Protection Agency, NIEHS, the Veterans Administration, and academic institutions met with investigators from the Soviet Union to exchange information and to develop protocols for replicate studies to be conducted in the laboratories of each country.

Bureau Cosponsors Radiofrequency Effects Workshop

A workshop on behavioral effects of microwave radiation was held March 16-19, 1982, in Midway, Utah. The meeting was sponsored by FDA's Bureau of Radiological Health, the Environmental Protection Agency, and the Office of Naval Research. It was attended by many U.S. scientists from academic institutions and government agencies engaged in research on microwave behavioral effects.

A variety of topics was addressed, including microwave-induced alterations of spontaneous and schedule-controlled behavior, drug-microwave behavioral synergisms, developmental effects, interspecies comparative considerations, and Eastern European research findings. Extensive discussions were conducted on the discrepancies in the current data base, the human health hazards associated with microwave-induced behavioral effects, and future research needs in this area of risk assessment. The workshop proceedings are being prepared for publication.

Bureau Staff Members Honored at FDA Awards Ceremony

Six Bureau of Radiological Health staff members and four Bureau groups were commended for exceptional contributions in promoting and administering the Agency's programs in radiation protection at the FDA's 22nd Annual Honor Awards Ceremony, June 17, 1982, in Rockville, Maryland.

Neil S. Goldstein, Associate Director for Management and Systems, and Walter E. Gundaker, Acting Director, Division of Compliance, were awarded the PHS Outstanding Service Medal--the highest award the PHS confers upon a Commissioned Officer. Mr. Goldstein received the medal in recognition of "sustained meritorious

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service and professional leadership of the administrative management operations for the Bureau of Radiological Health." Mr. Gundaker was recognized for "outstanding technical and administrative leadership in implementing for FDA the legislative responsibilities of the laws concerning radiological health and radiation-emitting medical devices."

Gideon Kantor, Division of Electronic Products, received the FDA Award of Merit--FDA's highest honor--for "outstanding service in research and development of improved radiofrequency medical devices, thus bringing recognition to the Agency as an international leader in the area."

The FDA Commissioner's Special Citation was awarded to Russell L. Carpenter, Division of Biological Effects, in recognition of his "outstanding contributions to the Food and Drug Administration's microwave research and radiation control programs which have stimulated studies by scientific organizations nationwide."

Robert T. Handren, Jr., Division of Compliance, received the PHS Commendation Medal for "sustained high quality performance in the regulation of coherent and non-coherent electronic light sources."

Robert J. Morton, Jr., Division of Training and Medical Applications, received the PHS Commendation Medal in recognition of "outstanding contributions to development and implementation of nationwide programs to optimize exposures in therapeutic radiology."

The Technical Reports Section, Office of Management and Systems, received the FDA Commendable Service Group Award for "sustained outstanding performance in providing superior consultation, editing, and production services for Bureau and Agency publications."

Three groups received both the FDA Commendable Service Group Award and the PHS Unit Commendation. The Quality Control Evaluation Section, Division of Compliance, was recognized for "outstanding accomplishments in supporting the Food and Drug Administration's regulatory effort governing diagnostic x-ray products." The Field Support Group, Division of Electronic Products, was recognized for "sustained superior performance in supporting FDA's performance standards enforcement and use control monitoring programs in the area of diagnostic x-ray testing." The Medical X-Ray Referral Criteria Group, Division of Training and Medical Applications, was recognized for "outstanding efforts in planning and conducting a nationwide program to reduce unnecessary medical radiation exposure through development of x-ray referral criteria."

At a separate awards ceremony for Bureau employees later the same day, PHS Achievement Medals were awarded to two Commissioned Officers of the Division of Compliance. Robert W. Faaland was recognized for "noteworthy contributions toward the development and implementation of the Bureau of Radiological Health's sunlamp products and ultraviolet lamp products compliance program," and Charles D. Stanley received the medal "in recognition of his unusually high quality and noteworthy contributions towards the planning, monitoring, evaluating, and coordination of radiological health field compliance programs."

Others recognized at the Bureau ceremony included George S. Komada, Division of Electronic Products, who received a posthumous PHS Citation for "sustained

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excellence in leadership and for his technical contributions in the radiological health area of consumer safety"; William M. Leach, Division of Biological Effects, who received a Community Service Award; and Cynthia J. Holibaugh, Office of Management and Systems, who received an OASH Special Recognition Award.

August 1982 Calendar of Events

The following is a list of August 1982 meetings of relevance to Bureau activities and the talks to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

24th Annual Meeting of the American Association of Physicists in Medicine, New Orleans, Louisiana, August 1 - 5.

"Attenuation Phantom for Estimating Patient Exposure from X-Ray Automatic Exposure Controlled Chest Examinations," Burton J. Conway, Richard E. Gross, John L. McCrohan, Jr., and Fred G. Rueter, Division of Training and Medical Applications, and Howard A. Goldstein, Johns Hopkins Hospital.

"Automatically Controlled Exposures of an Anthropomorphic Chest Phantom," Priscilla F. Butler and John L. McCrohan, Jr., Division of Training and Medical Applications, and Howard A. Goldstein, Johns Hopkins Hospital.

"A General Method for the Design of Tissue Substitutes and Test Objects for Use in Diagnostic Radiology," Robert J. Jennings, Division of Electronic Products.

"Investigation of Energy Response of Germanium Detectors and Correction of Measured Spectra by Means of Monte Carlo Simulation," Heang-Ping Chan, Chin-Tu Chen, and Kunio Doi, University of Chicago, and Thomas R. Fewell and Ralph E. Shuping, Division of Electronic Products.

"A New Dimension in Dual-Energy Tissue-Selective Imaging," Robert J. Jennings, Division of Electronic Products.

"On the Significance of Very Small Angle Scattered Radiation to Radiographic Imaging in the Mammography Energy Range," E. Phillip Muntz, University of Southern California, and Thomas R. Fewell and Robert J. Jennings, Division of Electronic Products.

"Performance Evaluation of an Attenuation Phantom in Estimating Patient Exposures for Automatic Exposure Controlled PA Chest Examinations," John L. McCrohan, Priscilla F. Butler, Burton J. Conway, Charles K. Showalter, and Penny R. Phillips, Division of Training and Medical Applications, and Howard A. Goldstein, Johns Hopkins Hospital.

"A Summary of the Results of a Self-Consistent Multiparameter Optimization of Mammography Systems Using Current Technology," E. Phillip Muntz and

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Hamid Jafroudi, University of Southern California, and Robert J. Jennings, Division of Electronic Products.

"Target Systems for Producing Clinically-Useful Quantities of Carbon-11 Using an Electron Linear Accelerator," Harley V. Piltingsrud, Division of Electronic Products.

Third World Congress of Nuclear Medicine and Biology, Paris, France, August 29 - September 2.

"Comparative Studies of I-123 and Tc-99m as Imaging Agents for Thyroid Disorders," Peter Paras, Office of Health Affairs; Eugene L. Saenger, Cincinnati General Hospital; and S. Spaventi and Z. Kusic, The Mladen Stojanovic Hospital, Zagreb, Yugoslavia.

"Progress in Gamma-Camera Quality Control: Resolution Measurements," Peter Paras, Office of Health Affairs; G. J. Hine, Boulder, Colorado; R. Adams, Loma Linda University; Donald L. Thompson, Division of Training and Medical Applications; and Charles P. Warr, Jr., and Richard J. Van Tuinen, Division of Electronic Products.

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BRH BULLETIN

bureau of radiological health

Monday, August 16, 1982 • Volume XVI, No. 8

In this issue:

- X-Ray Hazard from Pre-1964 Vacuum Spectrometers
- Internship Program for High School Students
- Corrective Action Plans
- New Bureau Publications
- September 1982 Calendar

Pre-1964 Vacuum Spectrometers Pose Serious X-Ray Hazard

At least four serious accidental radiation exposures have occurred recently with x-ray vacuum spectometers manufactured prior to 1964 by Philips Electronics Instruments.

X-ray vacuum spectrometers have self-contained shock-proof x-ray tube heads that permit close access to the x-ray tube port. It was not general practice to provide safety interlocks on the tube heads until 1962. In all four of the reported accidents, maintenance was being performed on the vacuum system, and the x-ray tube was removed while the system was inadvertently left on.

Safety upgrade kits have been available from Philips since 1968 to solve this problem. The kit includes interlocks for the x-ray tube head and the sample chamber cover and a fail-safe warning light that can be observed from anywhere around the machine.

Philips has previously attempted to locate owners of old equipment to advise them of the availability of the safety kit. In at least two of the reported incidents, the availability of the kit was known by the owners but the kit was not installed.

Because of the seriousness of the problem, the Bureau of Radiological Health urges anyone having a Philips vacuum spectrometer manufactured prior to 1964 to install the safety kit. To obtain information about the kit, please contact Dr. David Haas, Philips Electronic Instruments, 85 McKee Drive, Mahwah, New Jersey 07430, telephone (201) 529-3800. The spectrometers in question have serial numbers starting with 62 or less (i.e., 61xxx...).

Current standards for analytical x-ray equipment have been developed by the American National Standards Institute and published as National Bureau of Standards Handbook 111, "Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment." The Bureau encourages all users of analytical x-ray systems to review that standard and to upgrade the safety of their equipment, as appropriate. If the equipment does not have fail-safe "x-ray on" lights and safety interlocks, there is potential for serious accidental exposure.

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Bureau Sponsors Internship Program for Area High School Students

A volunteer internship program for high school students has begun its second year of operation at the Bureau of Radiological Health. High school students in the area are recommended to serve an internship period in which they learn and perform science-related tasks in connection with ongoing Bureau research.

The program was initiated to encourage students to consider science careers in the area of radiological health. Students are selected to serve for semester or summer terms of the school year, and earn science credit at the high school.

To date, 32 students from five Maryland high schools have participated in the program. Assignments have been largely in biological and physical research and testing, with jobs that involve the use of computers being particularly popular with the students. Other jobs have involved work in communications, including both library science and television production.

The program originated as a project of the Bureau's Equal Opportunity Advisory Committee.

Corrective Action Plans

During July 1982, the Bureau of Radiological Health approved three corrective action plans for products found in noncompliance with performance standards issued under the Radiation Control for Health and Safety Act, and one for a product found defective under the Act. The products involved are:

- 7 Davidson Optronics laser products, models D305L, D319, and 105-2686. The units failed to comply with the performance standard for laser products because they lacked the required certification, identification, and warning labels, and also lacked the eyepiece filters required to assure that only Class I levels of laser radiation are accessible through the viewing optics. The firm's corrective action plan consists of notifying users and sending each user a retrofit kit that contains the required labels, a revised user manual, and attenuation filters to be installed in the eyepieces. Corrections will be performed at no cost to users.

- 800 General Electric computer tomography devices--CT/T 7800, 7805, and 8800 systems--model numbers 46-186550G3 and 46-18550G4 x-ray controls below serial number 20858CN7, except model 46-186550G3 SN 13601CNO, 1624/CN2, 16242CN0, 17284CN3, 17644CN6, and 18226CN1, and model 46-186550G4 SN 1756CN0. The units were found defective in that they could emit electronic product radiation unnecessary to the accomplishment of their primary purpose, creating a risk of injury. The problem occurs if the x-ray tube target is heated beyond its ratings. Under these extreme circumstances, the tube enclosure may rupture. This type of target heating may occur because of loss of grid control during a CT scan at high technique factors or during the warmup period and unnecessary patient exposure could result if a patient was being diagnosed at the time of failure. The firm's corrective action plan calls for General Electric service personnel to visit each customer site and modify the units at no cost to users.

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- 15 Control Laser Corporation Class I laser tools incorporating solid state lasers and connected work stations. The firm has been granted an exemption from the requirement of the laser product performance standard for products with double-interlocked work stations. However, in order for the units to comply with the standard, the microswitch interlocks on the single-interlocked work stations must be replaced with "banana plugs." The corrective action plan consists of making this replacement at no cost to users.

- 3 Yoshida Panoura 8 and 8C panoramic dental x-ray units, imported by Kaycor, International, Inc. The machines failed to comply with the performance standard for diagnostic x-ray systems because there was a discrepancy in the mA accuracy statements, the x-ray beam was larger than the size of the image receptor, and the technique factors were not visible from the operator's position. Kaycor will notify users of the noncompliance and provide a new installation manual to correct the mA accuracy statement and to advise assemblers to install the x-ray control so that the indicated technique factors may be seen from the operator's position. Kaycor will also provide a new x-ray beam limiter (to be installed by the user) to reduce the size of the x-ray beam. Users will be provided with a return card to indicate they have received the installation manual and changed the x-ray beam limiter. All corrections will be made at no cost to users.

New Bureau Publications

The following publications are available for purchase from the National Technical Information Service, as indicated in the parentheses following the citation.

"Annual Report of the Division of Biological Effects Fiscal Year 1980" (FDA 82-8152), prepared by Division of Biological Effects staff. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-215500, $10.50 per paper copy, $4.00 for microfiche.)

"Guide for the Filing of Annual Reports (21 CFR, Subchapter J, Section 1002.11)" (FDA 82-8127), compiled by the Division of Compliance. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-214206, $9.00 per paper copy, $4.00 for microfiche.)

September 1982 Calendar of Events

The following is a list of September 1982 meetings of relevance to Bureau activities and the talks to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Meeting of Working Party on Afterloading in Radiation Therapy, Mexico City, Mexico, August 29 - September 3.

"United States Regulatory Experience with Radioactive Materials Used in Therapy," Gail D. Schmidt, Office of the Bureau Director.

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American Thyroid Association Meeting, Quebec, Canada, September 22 - 25.

"Dose Responses in Thyroid Tumor Inductions from I-131 and Localized Thyroid and Pituitary Irradiations in Rats," Wah Lee and Richard P. Chiacchierini, Division of Biological Effects; Bernard Shleien, Office of Health Affairs; and Norman C. Telles, Massachusetts Department of Public Health.

American College of Emergency Physicians Scientific Assembly, San Francisco, California, September 28 - October 1.

"Risk Assessment of Referral Criteria Use for Skull Radiography Following Head Trauma," Philip M. McClean and Harvey Rudolph, Division of Training and Medical Applications.

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bureau of radiological health

JUL

Monday, September 13, 1982 • Volume XVI, No. 9

In this issue:

- Radiofrequency Applicator Development
- Chest Phantom Pilot Study
- International Laser Safety Standard Development
- Evaluation of Hyperthermia Equipment for NCI
- Teleradiology Conference
- Corrective Action Plans
- October 1982 Calendar
- New Bureau Publications

Bureau Developing Uniform Deep Heating Radiofrequency Applicators

Engineers of the Electromagnetics Branch of the Bureau's Division of Electronic Products are developing a family of helical-coil radiofrequency applicators with a unique ability to deposit uniform heating throughout deep tissue. These applicators represent a significant improvement in the state of the art, and an application has been made for a patent.

Uniform deep heating in tissue has long been sought by medical investigators and clinicians for use in the treatment of deep-seated cancerous tumors (hyperthermia) and in diathermy treatments. Heat is known to be effective in the treatment of surface tumors, and such heating has been induced through the use of radiofrequency and microwave applicators. These older applicators, however, do not have the capability to cause energy to penetrate deeply and uniformly in tissue, and therefore cannot be used to heat deep tissues without excessively heating healthy surface tissues (skin and fat).

The helical coils under development at the Bureau overcome the surface heating problem while being able to produce uniform heating in simulated muscle (phantom) material. Another unique feature of the coils is that this heating, with a uniform cross section throughout phantoms, is concentrated at the center of the axial coil length. Phantom tissues located in the ends of the coil are not heated. This concentration deposits sufficient heat at radio frequencies to be effective in reaching temperatures considered necessary to treat tumors (45 °C).

The investigations and analyses have been performed on arm- and thigh-sized coils and phantoms. Future work will be directed toward development and testing of a human-sized torso or trunk coil and phantom. The arm-sized coil produced a temperature rise of 1.9 °C per minute with 100 watts of net power applied at 27.12 megahertz uniformly across the phantom muscle material at the coil's longitudinal center. Similarly, the thigh coil produced a temperature rise of 0.2 °C at 13.56 megahertz. For the arm coil, the muscle phantom material had a diameter of 6

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centimeters and was surrounded by 1 centimeter of simulated fat material; the thigh phantom's muscle material had a diameter of 12 centimeters and was surrounded by 2 centimeters of simulated fat material.

The results obtained to date by the Electromagnetics Branch engineers were presented in June 1982 at the IEEE Microwave Theory and Techniques Workshop on Medical Applications of Electromagnetic Energy in Dallas, Texas. An article describing the results, along with a method developed to predict within 10 percent the uniformity and amount of heating, will be submitted for publication in a professional journal early next year. A great deal of interest has already been expressed by clinicians and researchers who have learned of this unique development.

For further information about the applicators, please contact Paul S. Ruggera or Gideon Kantor, Bureau of Radiological Health (HFX-240), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-3840.

Chest Phantom Pilot Study Begins

An attenuation phantom that facilitates the estimation of average patient exposure during automatic exposure controlled (AEC) radiographic posterior-anterior (PA) chest procedures has been developed by the Bureau of Radiological Health. The 17-pound phantom called ("LucAl") is fabricated from Lucite and aluminum and has exit-beam characteristics similar to those provided by the lung fields of a 22- to 23-centimeter-thick patient. The Lucite and aluminum configuration was determined by matching narrow- and broad-beam exit spectra and broad-beam exit exposures behind the lung fields of a known patient-equivalent anthropomorphic chest phantom.

The LucAl phantom's performance has been clinically tested at a number of facilities employing a variety of chest techniques and equipment types. Entrance skin exposure values were determined at each facility for 40 to 120 patients with known PA dimensions. The mean patient exposure and a predicted exposure to a patient with a 22.5-centimeter PA dimension were computed for each facility and compared to the exposure estimate derived from the phantom. These data showed that LucAl can provide an estimate of patient exposure in chest facilities, regardless of technique, which is accurate to within ±15 percent. Since the phantom was designed to simulate the attenuation and scatter conditions provided by the lung regions, the use of the phantom is restricted to PA techniques that use either one or both lung-field AEC detectors (typically provided on the x-ray equipment).

The LucAl phantom and its survey protocol will be pilot tested by six state radiation control programs (West Virginia, New Hampshire, South Carolina, Pennsylvania, New Jersey, and Illinois) as part of their routine x-ray surveys. The main purpose of this pilot test is to identify any problems that may exist with the phantom and/or survey procedures as used in the field. The Sensitometric Technique for the Evaluation of Processing (STEP), reported in the July 19, 1982, BRH Bulletin, has been included as an integral part of the pilot survey procedure in order to assess the nature of film-chemistry-processor performance used in chest radiography. During the pilot test, exposure and technique data will be collected

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from AEC and manually controlled systems (using average techniques) in order to compare the optical densities of the phantom images. Examining the resulting ranges of optical densities may yield information on whether facilities are routinely producing higher (or lower) than normal density films and thus higher (or lower) than normal patient exposures.

The pilot study will run from September 1982 to the spring of 1983. Final changes will be made in LucAl and/or the survey procedures based on state experiences during the pilot tests.

Although the phantom was developed for use in Bureau/state survey programs such as NEXT, its general use in the evaluation of x-ray equipment by technologists, medical physicists, and equipment engineers is anticipated.

For further information on this project, please contact Priscilla F. Butler, Bureau of Radiological Health (HFX-78), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2436.

Bureau Participating in International Laser Standard Development

Two international safety standards for laser products are in the final stages of development. One is for radiation safety and the other for electrical safety. The focal point for this activity during the past year has been the Electro-Optics Branch of the Bureau's Division of Electronic Products.

Since 1974, the Bureau has been actively participating with other member countries of the International Electrotechnical Commission (IEC) in the development of the two standards. The IEC radiation safety standard has been modeled after the FDA laser product performance standard and the American National Standards Institute (ANSI) standard for the safe use of lasers. This standard, titled "Radiation Safety of Laser Products - Equipment Classification, Requirements, and User's Guide," is intended for use by manufacturers of laser products, users, and regulatory agencies. When finally published, this standard, with necessary variations for national purposes, will probably be adopted as an enforceable standard by many of the nations that manufacture or trade internationally in these products.

From the inception of this activity, the U.S. National Committee of the IEC has been responsible for both the chairmanship and the secretariat of IEC Technical Committee 76 (Laser Equipment). Mr. George Wilkening of Bell Telephone Laboratories has served as chairman of the Committee, while the Bureau has served in a key role by maintaining the secretariat. The current secretary is Electro-Optics Branch Chief Robert J. Landry, who in 1981 succeeded Henry J. L. Rechen, Deputy Director of the Division of Electronic Products. The Bureau, in maintaining the secretariat, coordinates the work and activities of the Committee.

In addition to the radiation standard, the IEC Committee has developed an electrical safety standard titled "Electrical Safety of Laser Equipment and Installations." Both the radiation and electrical standards have been recommended for publication by the IEC member nations. It is expected that both standards will be published in 1983.

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Hyperthermia Equipment Being Evaluated Under Agreement with NCI

The Bureau of Radiological Health has entered into an interagency agreement with the National Cancer Institute (NCI) to provide technical support to NCI's contractual program titled "Phase I Evaluation of Equipment for Hyperthermia Treatment of Cancer." Under the 5-year agreement, the Bureau's Division of Electronic Products (DEP) will provide NCI with technical assistance on the selection and analysis of heat generation and thermometry equipment to be used in the evaluation of hyperthermia equipment. DEP also will perform measurements on RF/microwave and ultrasound hyperthermia devices used at five contractor sites in order to characterize, compare, and calibrate this equipment.

In May 1982, several Bureau staff members participated in the first NCI contractor site visit at the University of Arizona. Also in attendance were personnel from the other contractor sites--the University of Utah, Stanford University, Massachusetts Institute of Technology, and M. D. Anderson Hospital in Houston. Discussions were held on equipment evaluation and testing, clinical data analysis, clinical data reporting formats, and new clinical research techniques. In addition, RF leakage measurements were made on several devices at the University of Arizona Medical Center. The next site visit is scheduled for November at M. D. Anderson Hospital.

Several key tasks have been completed at the Bureau under the interagency agreement. DEP's Electromagnetics Branch has developed and tested a precise thermometry calibration system for the special thermometers used in hyperthermia equipment. A computerized thermographic camera also has been completed and calibrated for use in RF heating studies. In addition, various RF phantom materials have been fabricated and tested to ensure equivalence with human tissue.

In the ultrasound area, DEP's Acoustics Branch has worked with a commercial manufacturer to design and develop a hyperthermia ultrasonic power meter. This device is a direct adaptation of an ultrasonic therapy wattmeter previously developed through a cooperative effort between the manufacturer and the Bureau. Two types of tissue equivalent phantom materials also have been developed in cooperation with two small manufacturers. Thermal measurements with several types of probes are now under way, with particular emphasis being placed on developing an accurate thermal assessment of the heat distribution in the phantom while minimizing the effect on the ultrasonic field.

Bureau Cosponsors Teleradiology Conference

The preliminary results of a 6-month field trial of a microcomputer-based teleradiology system were presented at a conference on August 19-20, 1982, at the Uniformed Services University of Health Sciences in Bethesda, Maryland. The conference was jointly sponsored by the Bureau of Radiological Health, Food and Drug Administration; Bureau of Community Health Services, Health Services Administration; Tri-Service Medical Information Systems Program (TRIMIS), Department of Defense; and the MITRE Corporation of McLean, Virginia.

Principal speakers at the conference included Dr. C. Everett Koop, Surgeon General of the United States Public Health Service; General William S. Augerson,

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Deputy Assistant Secretary of Defense; and General Quinn H. Becker, Deputy Surgeon General of the Army. Each was enthusiastic about the successful results of the field trial and the collaboration among the services.

Teleradiology is the electronic transmission of radiographic images from remote clinics without specialty services, to medical centers where radiologists are available. The teleradiology system was developed to provide timely access to radiology services to military personnel and civilians in remote areas. In the field trial, transmitting equipment was installed at one PHS and three military sites located 10 to 150 miles from the Malcolm Grow Medical Center at Andrews Air Force Base in Suitland, Maryland, where the images were interpreted.

Each x-ray examination performed at the clinics was digitized using a television camera and transmitted over 9600-baud (bits per second) dedicated telephone lines to the central site where the images were stored on magnetic disks. During regularly scheduled reading times, radiologists accessed the radiographs on the disks and displayed them on a series of video monitors for interpretation. A priority mode was also available for emergency cases. This permitted real-time consultation between the attending physicians at the clinic and the radiologists at the medical center.

Throughout the field trial, data were collected on the technical performance of the teleradiology system, and a panel of senior radiologists reviewed a sample of the 5,000 cases to determine the accuracy of video interpretation. An archive consisting of the 500 cases which were reviewed during the field trial has been established at the Bureau. This data base will be made available to qualified investigators interested in furthering the development of digital radiology.

A detailed report on the teleradiology field trial will be available in October 1982. Further information may be obtained by contacting Dr. Joseph N. Gitlin, Bureau of Radiological Health (HFX-23), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5323.

Corrective Action Plans

During August and the first week of September 1982, the Bureau of Radiological Health approved three corrective action plans for products found in noncompliance with performance standards issued under the Radiation Control for Health and Safety Act. The products are as follows:

- 16 X-Cel X-Ray Podiatry x-ray units manufactured and recalled by X-Cel X-Ray Corporation, Crystal Lake, Illinois. The products involved are model P-75M (mobile) and model P-75W (wall mount). All 16 units were introduced into U.S. commerce. The x-ray units were not equipped with means to limit the source-to-skin distance to a minimum of 30 centimeters. In addition, markings on removable apertures were not always legible, and the beam limiting device labels listed only one of two possible source-to-skin distances. After notifying each customer, X-Cel will ship the corrected part and label to each customer who will perform corrections per instructions from X-Cel.

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- 22 Supra "C" capacitor discharge mobile x-ray systems manufactured for and recalled by CGR Medical Corporation, Baltimore, Maryland. Nineteen units were introduced into U.S. commerce and three remain under the control of the recalling firm. Due to a difference in test parameters, the units failed the beam quality section of the performance standard for diagnostic x-ray systems because an inadequate aluminum filter was placed into each unit. CGR plans to notify each user, visit each user site, and repiace the current 1-mm filter with a 2-mm filter.

- 67 Toshiba model KCD-10M-6C-B capacitor discharge mobile x-ray units manufactured by Toshiba of Japan and imported by Toshiba Medical Systems, Carson, California. The recalled units were manufactured during the period of August 1979 through March 1982. This model failed to comply with the light localizer illuminance requirement of the performance standard for diagnostic x-ray systems. Toshiba personnel will notify each user, visit each user location, and adjust the voltage between terminals no. 44 and 45 of the unit to 13.5 volts under load conditions.

October 1982 Calendar of Events

The following is a list of October 1982 meetings of relevance to Bureau activities and the talks to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not been published, and copies are not available from the Bureau's publications office. If you wish further information on a talk or a copy of the material on which it is based, please contact the author(s) directly.

Annual Meeting of the American Academy of Family Physicians, San Francisco, California, October 4 - 7.

> Exhibit: "Optimizing Diagnostic X-Ray Use," Mary Ann Wollerton, Division of Training and Medical Applications.

University of Massachusetts Department of Electrical and Computer Engineering, Amherst, Massachusetts, October 7.

> "Do Engineers Have a Role in the Study of Microwave Biological Effects?" Mays L. Swicord, Division of Biological Effects.

IEEE Ultrasonic Symposium, San Diego, California, October 27-29.

> "Pulsed Ultrasound Measurements Using Circular and Annular Polymer Membrane Receivers," Gerald R. Harris, Division of Electronic Products, E. F. Carome, John Carroll University, and H. D. Dardy, Naval Research Laboratory.

Southeastern Chapter of the Society of Nuclear Medicine Meeting, Charlotte, North Caroiina, October 27 - 30.

> "Study of Radiopharmaceutical Quality Control at Central In-House Radiopharmacies," Philip J. Robbins, Division of Electronic Products, and Mary J. Daly,

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Timothy J. Benedict, and Frank Z. Wickham, Columbus, Ohio, Board of Pharmacy.

"A Study of Xenon Trap Performance," Richard Van Tuinen and Laurence W. Grossman, Division of Electronic Products, and P. Eastvold and J. Papendorf, Illinois Department of Nuclear Safety.

Sixth Annual Symposium on Computer Applications in Medical Care, Washington, D.C., October 30 - November 2.

New Bureau Publications

The following publications are available for purchase from the National Technical Information Service, as indicated in the parentheses following the citation.

"13th Annual National Conference on Radiation Control, May 2-6, 1981, Little Rock, Arkansas" (FDA 82-8054), proceedings compiled by the Bureau of Radiological Health. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-237298, $22.50 per paper copy, $4.00 for microfiche.)

"High-Yield Criteria for Panoramic Radiography" (FDA 82-8186), Stuart C. White and Alan B. Forsythe, University of California at Los Angeles; Project Officer: Lireka P. Joseph, Division of Training and Medical Applications. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-229543, $7.50 per paper copy, $4.00 for microfiche.)

"Report of State and Local Radiological Health Programs, Fiscal Year 1980" (FDA 82-8034), Carl I. Vassar, Jr., Richard A. Moats, and Virginia A. Matthews, Office of the Executive Director of Regional Operations. (National Technical Information Service, Springfield, Virginia 22161; Accession No. PB 82-250028, $7.50 per paper copy, $4.00 for microfiche.)

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